§ 882.5975 Human dura mater.

(a) Identification. Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Human Dura Mater.” See §882.1(e) for the availability of this guidance.

(c) Scope. The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.

[68 FR 70436, Dec. 18, 2003, as amended at 76 FR 36993, June 24, 2011]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

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Source: 45 FR 13684-13720, Feb. 26, 1980, unless otherwise noted.
§ 884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

1. For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

2. For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

3. For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring
life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;
(4) For assessing the risk of cardiovascular diseases;
(5) For use in diabetes management;
(6) For identifying or inferring the identity of a microorganism directly from clinical material;
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;
(8) For noninvasive testing as defined in §812.3(k) of this chapter; and
(9) For near patient testing (point of care).

Subpart B—Obstetrical and Gynecological Diagnostic Devices
§ 884.1040 Viscometer for cervical mucus.
(a) Identification. A viscometer for cervical mucus is a device that is intended to measure the relative viscoelasticity of cervical mucus collected from a female patient. Measurements of relative viscoelasticity are intended for use as an adjunct in the clinical evaluation of a female with chronic infertility, to determine the time of ovulation and the penetrability of cervical mucus to motile sperm.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §884.9.

§ 884.1050 Endocervical aspirator.
(a) Identification. An endocervical aspirator is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to evaluate endocervical tissue to detect malignant and premalignant lesions.
(b) Classification. Class II (performance standards).

§ 884.1060 Endometrial aspirator.
(a) Identification. An endometrial aspirator is a device designed to remove materials from the endometrium (the mucosal lining of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to study endometrial cytology (cells).
(b) Classification. Class II. The special controls for this device are:
(1) FDA's:
   (i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and
   (ii) “510(k) Sterility Review Guidance of 2/12/90 (K90–1),”
(2) Labeling:
   (i) Indication: Only to evaluate the endometrium, and
   (ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and
   (3) The sampling component is covered within vagina.

§ 884.1100 Endometrial brush.
(a) Identification. An endometrial brush is a device designed to remove samples of the endometrium (the mucosal lining of the uterus) by brushing its surface. This device is used to study endometrial cytology (cells).
(b) Classification. Class II. The special controls for this device are:
(1) FDA's:
   (i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and
   (ii) “510(k) Sterility Review Guidance of 2/12/90 (K90–1),”
(2) Labeling:
   (i) Indication: Only to evaluate the endometrium, and
   (ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and
   (3) Design and testing:
      (i) The sampling component is covered within the vagina, and
§ 884.1175 Endometrial suction curette and accessories.
(a) Identification. An endometrial suction curette is a device used to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction. This device is used to obtain tissue for biopsy or for menstrual extraction. This generic type of device may include catheters, syringes, and tissue filters or traps.
(b) Classification. Class II (performance standards).

§ 884.1185 Endometrial washer.
(a) Identification. An endometrial washer is a device used to remove materials from the endometrium (the mucosal lining of the uterus) by washing with water or saline solution and then aspirating with negative pressure. This device is used to study endometrial cytology (cells).
(b) Classification. Class II (performance standards).

§ 884.1300 Uterotubal carbon dioxide insufflator and accessories.
(a) Identification. A uterotubal carbon dioxide insufflator and accessories is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.
(b) Classification. Class II (performance standards).

§ 884.1425 Perineometer.
(a) Identification. A perineometer is a device consisting of a fluid-filled sack for intravaginal use that is attached to an external manometer. The devices measure the strength of the perineal muscles by offering resistance to a patient’s voluntary contractions of these muscles and is used to diagnose and to correct, through exercise, urinary incontinence or sexual dysfunction.
(b) Classification. Class II (performance standards).

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).
(a) Identification. The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

§ 884.1560 Fetal blood sampler.
(a) Identification. A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a
heparinized tube. The fetal blood pH is determined and used in the diagnosis of fetal distress and fetal hypoxia.

(b) **Classification.** Class II (performance standards).

§ 884.1600 **Transabdominal amnioscope (fetoscope) and accessories.**

(a) **Identification.** A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

(b) **Classification.** Class II (performance standards).

§ 884.1640 **Culdoscope and accessories.**

(a) **Identification.** A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables, and component parts.

(b) **Classification.** (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (non-inflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

§ 884.1660 **Transcervical endoscope (amnioscope) and accessories.**

(a) **Identification.** A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include obturators, instruments used through an operating channel, light...
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§ 884.1690 Hysteroscope and accessories.
(a) Identification. A hysteroscope is a device used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. It is used to perform diagnostic and surgical procedures other than sterilization. This generic type of device may include obturators and sheaths, instruments used through an operating channel, scope preheaters, light sources and cables, and component parts.
(b) Classification. (1) Class II (performance standards).
(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

§ 884.1700 Hysteroscopic insufflator.
(a) Identification. A hysteroscopic insufflator is a device designed to distend the uterus by filling the uterine cavity with a liquid or gas to facilitate viewing with a hysteroscope.
(b) Classification. (1) Class II (performance standards).
(2) Class I for tubing and tubing/filter fits which only include accessory instruments that are not used to effect intrauterine access, e.g., hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

§ 884.1720 Gynecologic laparoscope and accessories.
(a) Identification. A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: Trocar and cannula, instruments used through an operating channel, scope preheater, light source and cables, and component parts.
(b) Classification. (1) Class II (performance standards).
(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

§ 884.1730 Laparoscopic insufflator.
(a) Identification. A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.
(b) Classification. (1) Class II (performance standards).
§ 884.2050  Obstetric data analyzer.

(a) Identification. An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal status and recommendations for labor management and clinical interventions. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 3, 2000, for any obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has been found, on or before October 3, 2000, to be substantially equivalent to an obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other obstetric data analyzer described in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

§ 884.2225  Obstetric-gynecologic ultrasonic imager.

(a) Identification. An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include the following: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time.

(b) Classification. Class II (performance standards).

§ 884.2320  Fetal cardiac monitor.

(a) Identification. A fetal cardiac monitor is a device used to ascertain fetal heart activity during pregnancy and labor. The device is designed to separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction and relaxation of heart muscle) obtained from the maternal abdomen with external electrodes. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold. This generic type of device includes the “fetal cardiotachometer (with sensors)” and the “fetal electrocardiographic monitor.”

(b) Classification. Class II (performance standards).

§ 884.2620  Fetal electroencephalographic monitor.

(a) Identification. A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or a notice of completion of a PDP is required to be
§ 884.2640 Fetal phonocardiographic monitor and accessories.

(a) Identification. A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and other component parts.

(b) Classification. Class II (performance standards).

§ 884.2660 Fetal ultrasonic monitor and accessories.

(a) Identification. A fetal ultrasonic monitor is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, usually by means of continuous wave (doppler) echoscopy. The device is used to represent some physiological condition or characteristic in a measured value over a period of time (e.g., perinatal monitoring during labor) or in an immediately perceivable form (e.g., use of the ultrasonic stethoscope). This generic type of device may include the following accessories: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, and component parts. This generic type of device does not include devices used to image some relatively unchanging physiological structure or interpret a physiological condition, but does include devices which may be set to alarm automatically at a predetermined threshold value.

(b) Classification. Class II (performance standards).

§ 884.2675 Fetal scalp circular (spiral) electrode and applicator.

(a) Identification. A fetal scalp circular (spiral) electrode and applicator is a device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an external monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This generic type of device includes nonreusable spiral electrodes and reusable circular electrodes.

(b) Classification. Class II (performance standards).

§ 884.2685 Fetal scalp clip electrode and applicator.

(a) Identification. A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976. Any other fetal scalp clip electrode and applicator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 884.2700 Intrauterine pressure monitor and accessories.

(a) Identification. An intrauterine pressure monitor is a device designed to detect and measure intrauterine and amniotic fluid pressure with a catheter placed transcervically into the uterine cavity. The device is used to monitor intensity, duration, and frequency of uterine contractions during labor. This generic type of device may include the following accessories: signal analysis and display equipment, patient and equipment supports, and component parts.

(b) Classification. Class II (performance standards).

§ 884.2720 External uterine contraction monitor and accessories.

(a) Identification. An external uterine contraction monitor (i.e., the tokodynamometer) is a device used to monitor the progress of labor. It measures the duration, frequency, and relative pressure of uterine contractions with a transducer strapped to the maternal abdomen. This generic type of device may include an external pressure transducer, support straps, and other patient and equipment supports.

(b) Classification. Class II (performance standards).

§ 884.2730 Home uterine activity monitor.

(a) Identification. A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.

(b) Classification. Class II (special controls); guidance document (Class II Special Controls Guidance for Home Uterine Activity Monitors).

§ 884.2740 Perinatal monitoring system and accessories.

(a) Identification. A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays of the well-being of the fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to §§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720. This generic type of device may include the following accessories: Central monitoring system and remote repeaters, signal analysis and display equipment, patient and equipment supports, and component parts.

(b) Classification. Class II (performance standards).

§ 884.2800 Computerized Labor Monitoring System.

(a) Identification. A computerized labor monitoring system is a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.

(b) Classification. Class II (special controls). The special controls are the FDA guidance document entitled: “Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems.” See § 884.1(e) for availability of this guidance document.

§ 884.2900 Fetal stethoscope.

(a) Identification. A fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit the fetal heart sounds not only through sound channels by air conduction, but also through the user’s head by tissue conduction into the user’s ears. It does
not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §884.9.


§ 884.2960 Obstetric ultrasonic transducer and accessories.

(a) Identification. An obstetric ultrasonic transducer is a device used to apply ultrasonic energy to, and to receive ultrasonic energy from, the body in conjunction with an obstetric monitor or imager. The device converts electrical signals into ultrasonic energy, and vice versa, by means of an assembly distinct from an ultrasonic generator. This generic type of device may include the following accessories: coupling gel, preamplifiers, amplifiers, signal conditioners with their power supply, connecting cables, and component parts. This generic type of device does not include devices used to generate the ultrasonic frequency electrical signals for application.

(b) Classification. Class II (performance standards).

§ 884.2982 Liquid crystal thermographic system.

(a) A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for adjuncive use in diagnostic screening for detection of breast cancer or other uses—

(1) Identification. A nonelectrically powered or an AC-powered liquid crystal thermographic system for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) Classification. Class I (general controls).

(b) Telethermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses—

(1) Identification. A telethermographic system for use as the sole diagnostic screening tool for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) Classification. Class III.

(3) Date PMA or notice of completion of a PDP is required. As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See §884.3.

§ 884.2990 Breast lesion documentation system.

(a) Identification. A breast lesion documentation system is a device for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast examination.

(b) Classification. Class II (performance standards).

§ 884.3650 Fallopian tube prosthesis.

(a) Identification. A fallopian tube prosthesis is a device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.

(b) Classification. Class II (performance standards).

§ 884.3900 Vaginal stent.

(a) Identification. A vaginal stent is a device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.

(b) Classification. Class II (performance standards).

Subpart E—Obstetrical and Gynecological Surgical Devices

§ 884.4100 Endoscopic electrocautery and accessories.

(a) Identification. An endoscopic electrocautery is a device used to perform female sterilization under endoscopic observation. It is designed to coagulate fallopian tube tissue with a probe heated by low-voltage energy. This generic type of device may include the following accessories: electrical generators, probes, and electrical cables.

(b) Classification. Class II. The special controls for this device are:

(1) FDA’s:


(ii) “510(k) Sterility Review Guidance 2/12/90 (K-90),” and

(iii) “Guidance (‘Guidelines’) for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),”

§884.4160 Bipolar endoscopic coagulator-cutter and accessories.

(a) Identification. A bipolar endoscopic coagulator-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between two electrical contacts of a probe. This generic type of device may include the following accessories: an electrical generator, probes, and electrical cables.

(b) Classification. Class II. The special controls for this device are:

1. FDA’s:
3. “510(k) Sterility Review Guidance 2/12/90 (K-90),” and
4. “Guidance (‘Guidelines’) for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories),”


4. Labeling:
   (i) Indication: For female tubal sterilization, and
   (ii) Instructions for use:
      (A) Destroy at least 2 centimeters of the fallopian tubes,
      (B) Use a cut or undampened sinusoidal waveform,
      (C) Use a minimum power of 25 watts, and
      (D) For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.

§ 884.4250 Expandable cervical dilator.

(a) Identification. An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervical os.

(b) Classification. Class II (performance standards).

§ 884.4260 Hygroscopic Laminaria cervical dilator.

(a) Identification. A hygroscopic Laminaria cervical dilator is a device designed to dilate (stretch open) the cervical os by cervical insertion of a conical and expansible material made from the root of a seaweed (Laminaria digitata or Laminaria japonica). The device is used to induce abortion.

(b) Classification. Class II (performance standards).

§ 884.4270 Vibratory cervical dilators.

(a) Identification. A vibratory cervical dilator is a device designed to dilate the cervical os by stretching it with a power-driven vibrating probe head. The device is used to gain access to the uterus or to induce abortion, but is not to be used during labor when a viable fetus is desired or anticipated.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any vibratory cervical dilator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a vibratory cervical dilator that was in commercial distribution before May 28, 1976. Any other vibratory cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 884.4340 Fetal vacuum extractor.

(a) Identification. A fetal vacuum extractor is a device used to facilitate delivery. The device enables traction to be applied to the fetal head (in the birth canal) by means of a suction cup attached to the scalp and is powered by an external vacuum source. This generic type of device may include the cup, hosing, vacuum source, and vacuum control.

(b) Classification. Class II (performance standards).

§ 884.4400 Obstetric forceps.

(a) Identification. An obstetric forceps is a device consisting of two blades, with handles, designed to grasp and apply traction to the fetal head in the birth passage and facilitate delivery.

(b) Classification. Class II (performance standards).

§ 884.4500 Obstetric fetal destructive instrument.

(a) Identification. An obstetric fetal destructive instrument is a device designed to crush or pull the fetal body to facilitate the delivery of a dead or anomalous (abnormal) fetus. This generic type of device includes the cleidoclast, cranioclast, craniotribe, and destructive hook.

(b) Classification. Class II (performance standards).

§ 884.4520 Obstetric-gynecologic general manual instrument.

(a) Identification. An obstetric-gynecologic general manual instrument is one of a group of devices used
to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following:

1. An episiotomy scissors is a cutting instrument, with two opposed shearing blades, used for surgical incision of the vulvar orifice for obstetrical purposes.
2. A fiberoptic metal vaginal speculum is a metal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina.
3. A metal vaginal speculum is a metal instrument used to expose the interior of the vagina.
4. An umbilical scissors is a cutting instrument, with two opposed shearing blades, used to cut the umbilical cord.
5. A uterine clamp is an instrument used to hold the uterus by compression.
6. A uterine packer is an instrument used to introduce dressing into the uterus or vagina.
7. A vaginal applicator is an instrument used to insert medication into the vagina.
8. A vaginal retractor is an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.
9. A gynecological fibroid hook is an instrument used to exert traction upon a fibroid.
10. A pelvic meter (external) is an instrument used to measure the external diameters of the pelvis.

(b) Classification. Class I (general controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §884.9.

§884.4530 Obstetric-gynecologic specialized manual instrument.

(a) Identification. An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance.

This type of device consists of the following:

1. An amniotome is an instrument used to rupture the fetal membranes.
2. A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant.
3. An umbilical clamp is an instrument used to compress the umbilical cord.
4. A uterine curette is an instrument used to scrape and remove material from the uterus.
5. A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix.
6. A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus.
7. A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination.
8. A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix.
9. A gynecological cerclage needle is a looplike instrument used to suture the cervix.
10. A hook-type contraceptive intrauterine device (IUD) remover is an instrument used to remove an IUD from the uterus.
11. A gynecological fibroid screw is an instrument used to hold onto a fibroid.
12. A uterine sound is an instrument used to determine the depth of the uterus by inserting it into the uterine cavity.
13. A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina.
14. A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures.
15. A uterine tenaculum is a hook-like instrument used to seize and hold the cervix or fundus.
16. An internal pelvimeter is an instrument used within the vagina to measure the diameter and capacity of the pelvis.
§ 884.4550

(17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina.

(18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina.

(b) Classification. (1) Class II (performance standards).

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size buggies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.


§ 884.4550 Gynecologic surgical laser.

(a) Identification. A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue thermally or to remove tissue by radiant light energy. The device is used only in conjunction with a colposcope as part of a gynecological surgical system. A colposcope is a magnifying lens system used to examine the vagina and cervix.

(b) Classification. Class II (performance standards).

§ 884.4900 Obstetric table and accessories.

(a) Identification. An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes.

(b) Classification. Class II (performance standards).

§ 884.5050 Metreurynter-balloon abortion system.

(a) Identification. A metreurynter-balloon abortion system is a device used to induce abortion. The device is inserted into the uterine cavity, inflated, and slowly extracted. The extraction of the balloon from the uterus causes dilatation of the cervical os. This generic type of device may include pressure sources and pressure controls.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976. Any other metreurynter-balloon abortion system shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 884.5070 Vacuum abortion system.

(a) Identification. A vacuum abortion system is a device designed to aspirate transcervically the products of conception or menstruation from the uterus by using a cannula connected to a suction source. This device is used for pregnancy termination or menstrual regulation. This type of device may include aspiration cannula, vacuum source, and vacuum controller.

(b) Classification. Class II (performance standards).

§ 884.5100 Obstetric anesthesia set.

(a) Identification. An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended
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§ 884.5150 Nonpowered breast pump.
(a) Identification. A nonpowered breast pump is a manual suction device used to express milk from the breast.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9, if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

§ 884.5200 Hemorrhoid prevention pressure wedge.
(a) Identification. A hemorrhoid prevention pressure wedge provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.
(b) Classification. Class II (special controls). The special controls for this device are:
(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.
(2) The labeling must include specific instructions regarding the proper placement and use of the device.
(3) The device must be demonstrated to be biocompatible.
(4) Mechanical bench testing of material strength must demonstrate that the device will withstand forces encountered during use.
(5) Safety and effectiveness data must demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls.

§ 884.5225 Abdominal decompression chamber.
(a) Identification. An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient’s abdomen for the relief of abdominal pain during pregnancy or labor.
(b) Classification. Class III (premarket approval).
(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any abdominal decompression chamber that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an abdominal decompression chamber that was in commercial distribution before May 28, 1976. Any other abdominal decompression chamber shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 884.5250 Cervical cap.
(a) Identification. A cervical cap is a flexible cuplike receptacle that fits over the cervix to collect menstrual flow or to aid artificial insemination. This generic type of device is not for contraceptive use.
(b) Classification. Class II (performance standards).

§ 884.5300 Condom.
(a) Identification. A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive
and for prophylactic purposes (preventing transmission of sexually transmitted infections). The device may also be used to collect semen to aid in the diagnosis of infertility.

(b) **Classification.** (1) Class II (special controls) for condoms made of materials other than natural rubber latex, including natural membrane (skin) or synthetic.

(2) Class II (special controls) for natural rubber latex condoms. The guidance document entitled "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300" will serve as the special control. See §884.1(e) for the availability of this guidance document.

[73 FR 66538, Nov. 10, 2008]

§ 884.5310 **Condom with spermicidal lubricant.**

(a) **Identification.** A condom with spermicidal lubricant is a sheath which completely covers the penis with a closely fitting membrane with a lubricant that contains a spermicidal agent, nonoxynol–9. This condom is used for contraceptive and prophylactic purposes (preventing transmission of venereal disease).

(b) **Classification.** Class II (performance standards).

[47 FR 49022, Oct. 29, 1982]

§ 884.5320 **Glands sheath.**

(a) **Identification.** A glands sheath device is a sheath which covers only the glans penis or part thereof and may also cover the area in the immediate proximity thereof, the corona and frenulum, but not the entire shaft of the penis. It is indicated only for the prevention of pregnancy and not for the prevention of sexually-transmitted diseases.

(b) **Classification.** Class III (premarket approval).

(c) **Date premarket approval application (PMA) or notice of completion of premarket approval application (PDP) is required.** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 12, 2002, for any glands sheath that was in commercial distribution before May 28, 1976. Any other glands sheath shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.


§ 884.5330 **Female condom.**

(a) **Identification.** A female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. It is indicated for contraceptive and prophylactic (preventing the transmission of sexually transmitted diseases) purposes.

(b) **Classification.** Class III (premarket approval).

(c) **Date PMA or notice of completion of PDP is required.** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any female condom that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any female condom that was in commercial distribution before May 28, 1976. Any other female condom shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[65 FR 31455, May 18, 2000, as amended at 76 FR 50667, Aug. 16, 2011]

§ 884.5350 **Contraceptive diaphragm and accessories.**

(a) **Identification.** A contraceptive diaphragm is a closely fitting membrane placed between the posterior aspect of the pubic bone and the posterior vaginal fornix. The device covers the cervix completely and is used with a spermicide to prevent pregnancy. This generic type of device may include an introducer.

(b) **Classification.** Class II (performance standards).
§ 884.5360 Contraceptive intrauterine device (IUD) and introducer.

(a) Identification. A contraceptive intrauterine device (IUD) is a device used to prevent pregnancy. The device is placed high in the uterine fundus with a string extending from the device through the cervical os into the vagina. This generic type of device includes the introducer, but does not include contraceptive IUD’s that function by drug activity, which are subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act (see § 310.502).

(b) Classification. Class III (premarket approval).

(c) Labeling. Labeling requirements for contraceptive IUD’s are set forth in § 801.427.

(d) Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before August 4, 1986, for any IUD and introducer that was in commercial distribution before May 28, 1976, or that has on or before August 4, 1986, been found to be substantially equivalent to an IUD and introducer that was in commercial distribution before May 28, 1976. Any other IUD and introducer shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 884.5380 Contraceptive tubal occlusion device (TOD) and introducer.

(a) Identification. A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close a fallopian tube with a mechanical structure, e.g., a band or clip on the outside of the fallopian tube or a plug or valve on the inside. The devices are used to prevent pregnancy.

(b) Classification. Class II (performance standards).

§ 884.5400 Menstrual cup.

(a) Identification. A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

(b) Classification. Class II (performance standards).

§ 884.5425 Scented or scented deodorized menstrual pad.

(a) Identification. A scented or scented deodorized menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual pad) or for deodorizing purposes (scented deodorized menstrual pad). This generic type of device includes sterile scented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with added antimicrobial agents or other drugs.

(b) Classification. (1) Class I (general controls) for menstrual pads made of common cellulosic and synthetic material with an established safety profile. The devices subject to this paragraph (b)(1) are exempt from the premarket notification procedures in subpart E of

§ 884.5435 Unscented menstrual pad. 

(a) Identification. An unscented menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. This generic type of device includes sterile unscented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.

(b) Classification. Class I (general controls).


§ 884.5435 Unscented menstrual pad. 

(a) Identification. An unscented menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. This generic type of device includes sterile unscented menstrual pads used for medically indicated conditions, but does not include the intralabial pads and reusable menstrual pads.

(b) Classification. Class II (special controls) for scented or scented deodorized menstrual pads made of materials not described in paragraph (b)(1).


§ 884.5460 Scented or scented deodorized menstrual tampon. 

(a) Identification. A scented or scented deodorized menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.

(b) Classification. Class II (performance standards).


§ 884.5920 Vaginal insufflator. 

(a) Identification. A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §884.9.
§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.

(a) Identification. A powered vaginal muscle stimulator is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is intended and labeled for therapeutic use in increasing muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any powered vaginal muscle stimulator for therapeutic use that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a powered vaginal muscle stimulator that was in commercial distribution before May 28, 1976. Any other powered vaginal muscle stimulator for therapeutic use shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.


§ 884.5960 Genital vibrator for therapeutic use.

(a) Identification. A genital vibrator for therapeutic use is an electrically operated device intended and labeled for therapeutic use in the treatment of sexual dysfunction or as an adjunct to Kegel’s exercise (tightening of the muscles of the pelvic floor to increase muscle tone).

(b) Classification. Class II (performance standards).

Subpart G—Assisted Reproduction Devices

SOURCE: 63 FR 48436, Sept. 10, 1998, unless otherwise noted.

§ 884.6100 Assisted reproduction needles.

(a) Identification. Assisted reproduction needles are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to obtain gametes from the body or introduce gametes, zygote(s), preembryo(s) and/or embryo(s) into the body. This generic type of device may include a single or double lumen needle and component parts, including needle guides, such as those used with ultrasound.

(b) Classification. Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6110 Assisted reproduction catheters.

(a) Identification. Assisted reproduction catheters are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to introduce or remove gametes, zygote(s), preembryo(s), and/or embryo(s) into or from the body. This generic type of device may include catheters, cannulae, introducers, dilators, sheaths, stylets, and component parts.

(b) Classification. Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization
§ 884.6120 Assisted reproduction accessories.

(a) Identification. Assisted reproduction accessories are a group of devices used during assisted reproduction procedures, in conjunction with assisted reproduction needles and/or assisted reproduction catheters, to aspirate, incubate, infuse, and/or maintain temperature. This generic type of device may include:

(1) Powered aspiration pumps used to provide low flow, intermittent vacuum for the aspiration of ova.

(2) Syringe pumps (powered or manual) used to activate a syringe to infuse or aspirate small volumes of fluid during assisted reproduction procedures.

(3) Collection tube warmers, used to maintain the temperature of oocyte collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the oocyte during manipulation.

(4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature.

(5) Cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature.

(b) Classification. Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6130 Assisted reproduction microtools.

(a) Identification. Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold, or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.

(b) Classification. Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing).

§ 884.6140 Assisted reproduction micropipette fabrication instruments.

(a) Identification. Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) or other similar assisted reproduction procedures.

(b) Classification. Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

(a) Identification. Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

(b) Classification. Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6160 Assisted reproduction labware.

(a) Identification. Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures. These include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other vessels that come into physical contact with gametes, embryos or tissue culture media.

(b) Classification. Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing).

§ 884.6170 Assisted reproduction water and water purification systems.

(a) Identification. Assisted reproduction water purification systems are devices specifically intended to generate high quality, sterile, pyrogen-free water for reconstitution of media used
for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. These devices may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. These devices also include bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer, or storage of gametes or embryos for IVF or other assisted reproduction procedures.

(b) **Classification.** Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, water quality testing, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6180 Reproductive media and supplements.

(a) **Identification.** Reproductive media and supplement are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, acid solutions used to treat gametes or embryos, rinsing solutions, sperm separation media, supplements, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage. Supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).

(b) **Classification.** Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6190 Assisted reproductive microscopes and microscope accessories.

(a) **Identification.** Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are classified under assisted reproduction accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, dissecting microscopes and inverted stage microscopes.

(b) **Classification.** Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

§ 884.6200 Assisted reproduction laser system.

(a) **Identification.** The assisted reproduction laser system is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

(b) **Classification.** Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems.” See § 884.1(e) for the availability of this guidance document.

[69 FR 77624, Dec. 28, 2004]

PART 886—OPHTHALMIC DEVICES

Subpart A—General Provisions

Sec. 886.1 Scope.

886.3 Effective dates of requirement for premarket approval.

886.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

886.1040 Ocular esthesiometer.

886.1050 Adaptometer (biophotometer).

886.1070 Anomaloscope.

886.1090 Haidinger brush.

886.1120 Ophthalmic camera.

886.1140 Ophthalmic chair.

886.1150 Visual acuity chart.

886.1160 Color vision plate illuminator.

886.1170 Color vision tester.

886.1190 Distometer.

886.1200 Optokinetic drum.

886.1220 Corneal electrode.

886.1250 Euthyscope.

886.1270 Exophthalmometer.

886.1290 Fixation device.

886.1300 Afterimage flasher.