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

(68 FR 44415, Aug. 27, 2003)

**Subpart D—Obstetrical and Gynecological Prosthetic Devices**

§ 884.3200 **Cervical drain.**

(a) **Identification.** A cervical drain is a device designed to provide an exit channel for draining discharge from the cervix after pelvic surgery.

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

§ 884.3575 **Vaginal pessary.**

(a) **Identification.** A vaginal pessary is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse (falling down of uterus), uterine reposition (backward displacement), or gynecologic hernia.

(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),”


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.


§ 884.4120 **Gynecologic electrocautery and accessories.**

(a) **Identification.** A gynecologic electrocautery is a device designed to destroy tissue with high temperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual
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observation. This generic type of device may include the following accessories: an electrical generator, a probe, and electrical cables.

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

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

(a) Identification. A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through 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:
   (ii) “510(k) Sterility Review Guidance 2/12/90 (K–90),” and
   (iii) “Guidance (‘Guidelines’) for Evaluation of Laparoscopic Bipolar and Thermal Coaguclators (and Accessories),”


(3) American National Standards Institute/American Association for Medical Instrumentation’s HF–18, 1993, “Electrosurgical Devices,”

(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.

§ 884.4160 Unipolar endoscopic coagulator-cutter and accessories.

(a) Identification. A unipolar endoscopic coagulator-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a grounding plate. It is used in female sterilization and in other operative procedures under endoscopic observation. This generic type of device may include the following accessories: an electrical generator, probes and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hysteroscopic observation.

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

§ 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 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 expandable 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 an expandable cervical dilator that was in commercial distribution before May 28, 1976. Any other expandable cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 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 II (performance standards).

(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 pelvimeter (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 grasp, cut, 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.

(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 bougies), 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.
§ 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 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 for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both.

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

§ 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.

§ 884.5160 Powered breast pump.

(a) Identification. A powered breast pump in an electrically powered suction device used to express milk from the breast.

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