§ 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 (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 retroposition (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).”