

is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

[53 FR 1566, Jan. 20, 1988, as amended at 55 FR 48441, Nov. 20, 1990; 66 FR 46953, Sept. 10, 2001]

### 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:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(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),"

(2) International Electrotechnical Commission's IEC 60601-1-AM2 (1995-03), Amendment 2, "Medical Electrical Equipment—Part 1: General Requirements for Safety,"

(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.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

#### § 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 observation. This generic type of device may include the following accessories: an electrical generator, a probe, and electrical cables.

**§ 884.4150**

(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:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,'" "

(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)," "

(2) International Electrotechnical Commission's IEC 60601-1-AM2 (1995-03), Amendment 2, "Medical Electrical Equipment—Part 1: General Requirements for Safety," "

(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.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

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**§ 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.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

**§ 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*