Food and Drug Administration, HHS

§ 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

Subpart A—General Provisions

Sec.
884.1 Scope.
884.3 Effective dates of requirement for premarket approval.
884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Obstetrical and Gynecological Diagnostic Devices

884.1040 Viscometer for cervical mucus.
884.1050 Endocervical aspirator.
884.1060 Endometrial aspirator.
884.1100 Endometrial brush.
884.1175 Endometrial suction curette and accessories.
884.1185 Endometrial washer.
884.1300 Uterotubal carbon dioxide insufflator and accessories.
884.1425 Perineometer.
884.1550 Amniotic fluid sampler (amniocentesis tray).
884.1560 Fetal blood sampler.
884.1600 Transabdominal amnioscope (fenoscope) and accessories.
884.1650 Colposcope.
884.1660 Cystoscope and accessories.
884.1680 Transcervical endoscope (amnioscope) and accessories.
884.1700 Hysteroscope and accessories.
884.1720 Gynecologic laparoscope and accessories.
884.1730 Laparoscopic insufflator.

Subpart C—Obstetrical and Gynecological Monitoring Devices

884.2050 Obstetric data analyzer.
884.2225 Obstetric-gynecologic ultrasonic imager.
884.2250 Fetal cardiac monitor.
884.2260 Fetal electroencephalographic monitor.
884.2265 Fetal phonocardiographic monitor and accessories.
884.2266 Fetal ultrasonic monitor and accessories.
884.2267 Fetal scalp circular (spiral) electrode and applicator.
884.2268 Fetal scalp coil electrode and applicator.
884.2270 Intrauterine pressure monitor and accessories.
884.2272 External uterine contraction monitor and accessories.
884.2273 Home uterine activity monitor.
884.2275 Perinatal monitoring system and accessories.
884.2280 Computerized labor monitoring system.
884.2290 Fetal stethoscope.
884.2295 Obstetric ultrasonic transducer and accessories.
884.2298 Telethermographic system.
884.2299 Liquid crystal thermographic system.
884.2300 Breast lesion documentation system.

Subpart D—Obstetrical and Gynecological Prosthetic Devices

884.2300 Cervical drain.
884.2375 Vaginal pessary.
884.2376 Fallopian tube prosthesis.
884.2390 Vaginal stent.

Subpart E—Obstetrical and Gynecological Surgical Devices

884.2400 Endoscopic electrocautery and accessories.
884.2410 Gynecologic electrocautery and accessories.
884.2415 Bipolar endoscopic coagulator-cutter and accessories.
884.2416 Unipolar endoscopic coagulator-cutter and accessories.
884.2420 Expandable cervical dilator.
884.2425 Hygroscopic Laminaria cervical dilator.
884.2430 Vibratory cervical dilators.
884.2431 Fetal vacuum extractor.
884.2440 Obstetric forceps.
884.2450 Obstetric fetal destructive instrument.
884.2451 Obstetric-gynecologic general manual instrument.
884.2452 Obstetric-gynecologic specialized manual instrument.
884.2453 Obstetric-gynecologic surgical laser.
884.2455 Obstetric table and accessories.