

§ 882.5960

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987]

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

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

§ 882.5970 Cranial orthosis.

(a) *Identification.* A cranial orthosis is a device that is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification.* Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

[63 FR 40651, July 30, 1998]

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.

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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 (fetoscope) and accessories.

884.1630 Colposcope.

884.1640 Culdoscope and accessories.

884.1660 Transcervical endoscope (amnioscope) and accessories.

884.1690 Hysteroscope and accessories.

884.1700 Hysteroscopic insufflator.

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.

884.2600 Fetal cardiac monitor.

884.2620 Fetal electroencephalographic monitor.

884.2640 Fetal phonocardiographic monitor and accessories.

884.2660 Fetal ultrasonic monitor and accessories.

884.2675 Fetal scalp circular (spiral) electrode and applicator.

884.2685 Fetal scalp clip electrode and applicator.

884.2700 Intrauterine pressure monitor and accessories.

884.2720 External uterine contraction monitor and accessories.

884.2730 Home uterine activity monitor.

884.2740 Perinatal monitoring system and accessories.

884.2900 Fetal stethoscope.

884.2960 Obstetric ultrasonic transducer and accessories.

884.2980 Telethermographic system.

884.2982 Liquid crystal thermographic system.

Subpart D—Obstetrical and Gynecological Prosthetic Devices

884.3200 Cervical drain.

884.3575 Vaginal pessary.

884.3650 Fallopian tube prosthesis.

884.3900 Vaginal stent.

Subpart E—Obstetrical and Gynecological Surgical Devices

884.4100 Endoscopic electrocautery and accessories.