

§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.

(a) *Identification.* A powered vaginal muscle stimulator is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is intended and labeled for therapeutic use in increasing muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

(b) *Classification.* Class III (premarket approval).

(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 § 884.3.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987]

§ 884.5960 Genital vibrator for therapeutic use.

(a) *Identification.* A genital vibrator for therapeutic use is an electrically operated device intended and labeled for therapeutic use in the treatment of sexual dysfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone).

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

PART 886—OPHTHALMIC DEVICES**Subpart A—General Provisions**

Sec.

886.1 Scope.

886.3 Effective dates of requirement for premarket approval.

886.9 Limitations of exemptions from section 510(k) of the act.

Subpart B—Diagnostic Devices

886.1040 Ocular esthesiometer.
 886.1050 Adaptometer (biophotometer).
 886.1070 Anomaloscope.
 886.1090 Haidlinger brush.
 886.1120 Ophthalmic camera.
 886.1140 Ophthalmic chair.
 886.1150 Visual acuity chart.
 886.1160 Color vision plate illuminator.
 886.1170 Color vision tester.
 886.1190 Distometer.
 886.1200 Optokinetic drum.
 886.1220 Corneal electrode.
 886.1250 Euthyscope.
 886.1270 Exophthalmometer.

886.1290 Fixation device.
 886.1300 Afterimage flasher.
 886.1320 Fornixscope.
 886.1330 Amsler grid.
 886.1340 Haploscope.
 886.1350 Keratoscope.
 886.1360 Visual field laser instrument.
 886.1375 Bagolini lens.
 886.1380 Diagnostic condensing lens.
 886.1385 Polymethylmethacrylate (PMMA) diagnostic contact lens.
 886.1390 Flexible diagnostic Fresnel lens.
 886.1395 Diagnostic Hruby fundus lens.
 886.1400 Maddox lens.
 886.1405 Ophthalmic trial lens set.
 886.1410 Ophthalmic trial lens clip.
 886.1415 Ophthalmic trial lens frame.
 886.1420 Ophthalmic lens gauge.
 886.1425 Lens measuring instrument.
 886.1430 Ophthalmic contact lens radius measuring device.
 886.1435 Maxwell spot.
 886.1450 Corneal radius measuring device.
 886.1460 Stereopsis measuring instrument.
 886.1500 Headband mirror.
 886.1510 Eye movement monitor.
 886.1570 Ophthalmoscope.
 886.1605 Perimeter.
 886.1630 AC-powered photostimulator.
 886.1640 Ophthalmic preamplifier.
 886.1650 Ophthalmic bar prism.
 886.1655 Ophthalmic Fresnel prism.
 886.1660 Gonioscopic prism.
 886.1665 Ophthalmic rotary prism.
 886.1670 Ophthalmic isotope uptake probe.
 886.1680 Ophthalmic projector.
 886.1690 Pupillograph.
 886.1700 Pupillometer.
 886.1750 Skiascopic rack.
 886.1760 Ophthalmic refractometer.
 886.1770 Manual refractor.
 886.1780 Retinoscope.
 886.1790 Nearpoint ruler.
 886.1800 Schirmer strip.
 886.1810 Tangent screen (campimeter).
 886.1840 Simulatan (including crossed cylinder).
 886.1850 AC-powered slitlamp biomicroscope.
 886.1860 Ophthalmic instrument stand.
 886.1870 Stereoscope.
 886.1880 Fusion and stereoscopic target.
 886.1905 Nystagmus tape.
 886.1910 Spectacle dissociation test system.
 886.1930 Tonometer and accessories.
 886.1940 Tonometer sterilizer.
 886.1945 Transilluminator.

Subpart C [Reserved]**Subpart D—Prosthetic Devices**

886.3100 Ophthalmic tantalum clip.
 886.3130 Ophthalmic conformer.
 886.3200 Artificial eye.
 886.3300 Absorbable implant (scleral buckling method).