[Code of Federal Regulations]
[Title 21, Volume 8]
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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 882 -- NEUROLOGICAL DEVICES

Subpart F--Neurological Therapeutic Devices

Sec. 882.5800 Cranial electrotheraphy stimulator.

(a) *Identification.* A cranial electrotheraphy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

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

(c) *Date a 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; 60 FR 43969, Aug. 24, 1995; 62 FR 30457, June 4, 1997]

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