AUTHORITY: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

SOURCE: 51 FR 26364, July 22, 1986, unless otherwise noted.

## Subpart A—General

### § 814.1 Scope.

(a) This part implements section 515 of the act by providing procedures for the premarket approval of medical devices intended for human use.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(c) This part applies to any class III medical device, unless exempt under section 520(g) of the act, that:

(1) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II; or

(2) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under section 515(b) of the act; or

(3) Was regulated by FDA as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by section 520(1) of the act.

(d) This part amends the conditions to approval for any PMA approved before the effective date of this part. Any condition to approval for an approved PMA that is inconsistent with this part is revoked. Any condition to approval for an approved PMA that is consistent with this part remains in effect.

EFFECTIVE DATE NOTE: At 75 FR 16350, Apr. 1, 2010, § 814.1 was amended by revising paragraph (a), effective Aug. 16, 2010. For the convenience of the user, the revised text is set forth as follows:

**§ 814.1 Scope.**

(a) This section implements sections 515 and 515A of the act by providing procedures for the premarket approval of medical devices intended for human use.

* * * * *

### § 814.2 Purpose.

The purpose of this part is to establish an efficient and thorough device review process—

(a) To facilitate the approval of PMA's for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval; and

(b) To ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval. This part shall be construed in light of these objectives.

EFFECTIVE DATE NOTE: At 75 FR 16350, Apr. 1, 2010, § 814.2 was revised, effective Aug. 16, 2010. For the convenience of the user, the revised text is set forth as follows: