

## § 860.93

## 21 CFR Ch. I (4-1-01 Edition)

accompanied by references to the sources containing such data;

(3) An identification of the risks to health (if any) presented by the device;

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with § 860.95;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement;

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the Dockets Management Branch's office upon receipt and are available to the public upon request.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with § 860.95;

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with § 860.93(b).

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992; 64 FR 404, Jan. 5, 1999]

### **§ 860.93 Classification of implants, life-supporting or life-sustaining devices.**

(a) The classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing together with references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification

panel, together with supporting documentation and data satisfying the requirements of §860.7 and an identification of the risks to health, if any, presented by the device.

**§ 860.95 Exemptions from sections 510, 519, and 520(f) of the act.**

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the act: Section 510 (registration, product listing and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice regulations).

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the act the device is to be exempted from, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

**Subpart C—Reclassification**

**§ 860.120 General.**

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(1) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in §860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within

that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(1). The Commissioner may initiate the reclassification of a device classified into class III under sections 513(f) and 520(1) of the act.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

**§ 860.123 Reclassification petition: Content and form.**

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that \_\_\_ device(s) be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of §860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;