
21 U.S. Code § 360m

Accredited persons

(a) In general

(1) Review and classification of devices

Not later than 1 year after November 21, 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 360(k) of this title and making recommendations to the Secretary regarding the initial classification of devices under section 360c(f)(1) of this title.

(2) Requirements regarding review

(A) In general

In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

(B) Time period for review

Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

(C) Special rule

The Secretary may change the initial classification under section 360c(f)(1) of this title that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 360(k) of this title for the device, a statement explaining in detail the reasons for the change.

(3) Certain devices

(A) In general

An accredited person may not be used to perform a review of—

- (i) a class III device;
- (ii) a device classified under section 360c(f)(2) of this title or designated under section 360e-3(d) ⁽¹⁾ of this title;
- (iii) a device that is intended to be permanently implantable, life sustaining, or life supporting, unless otherwise determined by the Secretary in accordance with subparagraph (B)(i)(II) and listed as eligible for review under subparagraph (B)(iii); or
- (iv) a device that is of a type, or subset of a type, listed as not eligible for review under subparagraph (B)(iii).

(B) Designation for review

The Secretary shall—

(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person, including—

(I) the risk of the device type, or subset of such device type; and

(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for permitting the review by an accredited person of such device type or subset;

(ii) not later than 24 months after the date on which the Secretary issues such draft guidance, finalize such guidance; and

(iii) beginning on the date such guidance is finalized, designate and post on the internet website of the Food and Drug Administration, an updated list of class I and class II device types, or subsets of such device types, and the Secretary's determination with respect to whether each such device type, or subset of a device type, is eligible or not eligible for review by an accredited person under this section based on the factors described in clause (i).

(C) Interim rule

Until the date on which the updated list is designated and posted in accordance with subparagraph (B) (iii), the list in effect on August 18, 2017, shall be in effect.

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