

105TH CONGRESS
1ST SESSION

H. R. 1527

To amend the Federal Food, Drug, and Cosmetic Act with respect to the classification of and performance standards for devices.

IN THE HOUSE OF REPRESENTATIVES

MAY 1, 1997

Mr. UPTON (for himself, Ms. ESHOO, Mr. GREENWOOD, Mr. TOWNS, and Mr. HALL of Texas) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the classification of and performance standards for devices.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCES TO FEDERAL**
4 **FOOD, DRUG, AND COSMETIC ACT.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Medical Device Regulatory Flexibility Act”.

7 (b) REFERENCES TO FEDERAL FOOD, DRUG, AND
8 COSMETIC ACT.—Except as otherwise expressly provided,
9 whenever in this Act an amendment or repeal is expressed

1 in terms of an amendment to, or repeal of, a section or
2 other provision, the reference shall be considered to be
3 made to a section or other provision of the Federal Food,
4 Drug, and Cosmetic Act.

5 **SEC. 2. INITIAL CLASSIFICATION.**

6 Section 513(f) (21 U.S.C. 360c(f)) is amended—

7 (1) in paragraph (1) in the last sentence, by
8 striking “paragraph (2)” and inserting “paragraph
9 (2) or (3)”;

10 (2) by redesignating paragraphs (2) and (3) as
11 paragraphs (3) and (4), respectively; and

12 (3) by inserting after paragraph (1) the follow-
13 ing new paragraph:

14 “(2)(A) Any person who submits a report under sec-
15 tion 510(k) for a type of device that has not been pre-
16 viously classified and which is classified into class III
17 under paragraph (1), may request that the Secretary clas-
18 sify the device in class I or II, under criteria set forth
19 in subparagraphs (A) through (B) of subsection (a)(1),
20 within 30 days of receiving written notice of the classifica-
21 tion. Such request shall describe the device and provide
22 the reasons supporting such person’s recommended classi-
23 fication for the device based on specified classification
24 criteria.

1 “(B) Not later than 60 days after the date of the
2 request for classification under criteria set forth in sub-
3 paragraphs (A) through (B) of subsection (a)(1), the Sec-
4 retary shall by order classify the device and notify in writ-
5 ing the person who submitted such request of the classi-
6 fication. Such classification shall be the initial classifica-
7 tion of the device for purposes of paragraph (1). Any de-
8 vice which is classified into class III under this subpara-
9 graph shall be deemed adulterated within the meaning of
10 section 501(f)(1)(B) until approved under section 515 or
11 exempted from such approval under section 520(g).”.

12 **SEC. 3. DEVICE STANDARDS.**

13 (a) **ALTERNATIVE PROCEDURE.**—Section 514 (21
14 U.S.C. 360d) is amended by adding at the end thereof
15 the following:

16 “Listing of Recognized Standards

17 “(c)(1) The Secretary may, through publication in
18 the Federal Register, issue notices to identify and list na-
19 tionally and internationally recognized standards which—

20 “(A) shall be the special controls to which per-
21 sons may certify compliance for purposes of the spe-
22 cial controls required by section 513(a)(1)(B);

23 “(B) the Secretary may for purposes of device
24 classification use in establishing the equivalence of
25 one device to another; and

1 “(C) may be used by the Secretary in consider-
2 ing an application for premarket approval of a class
3 III device.

4 “(2) The Secretary may remove from the list of
5 standards established under paragraph (1) a standard
6 which the Secretary determines is not reliable for the pur-
7 pose set out in paragraph (1).

8 “(3) The Secretary shall accept a certification that
9 a device conforms to a standard listed under paragraph
10 (1), except that the Secretary may, at any time, request
11 the person who submitted the certification to submit the
12 data and information which such person relied upon in
13 making such certification. A person who submitted such
14 a certification shall maintain such data and information
15 for a period of 2 years after the submission of such certifi-
16 cation.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) SECTION 514(a).—Section 514(a) (21 U.S.C.
19 360d(a)) is amended by striking “established under
20 this section” each place it occurs and inserting “es-
21 tablished under subsection (b) or listed under sub-
22 section (c)”

23 (2) ADULTERATED DEVICE.—Section 501(e)
24 (21 U.S.C. 351(e)) is amended by striking “estab-
25 lished” and inserting “established or listed”.

1 (3) PROHIBITED ACTS.—Section 301 (21
2 U.S.C. 331) is amended by adding at the end the
3 following:
4 “(u) The falsification of a certification under section
5 514(c)(3) or the failure or refusal to provide data or infor-
6 mation requested by the Secretary under such section.”.

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