

112TH CONGRESS
2D SESSION

S. 2067

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device regulation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 2, 2012

Mr. CASEY (for himself and Mr. MCCAIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device regulation, and for other purposes.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Safe, Efficient, and Transparent Medical Device Ap-
6 proval Act” or the “SET Device Act”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Establishment of schedule and promulgation of regulation.
- Sec. 4. Modification of de novo application process.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

3 (1) Under the Safe Medical Devices Act of
4 1990 (Public Law 101–629), Congress amended sec-
5 tion 515 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 360e) to require the Food and Drug
7 Administration to reclassify preamendment class III
8 devices to a lower class or to require them to go
9 through the premarket approval process.

10 (2) The Food and Drug Administration has not
11 yet complied with the mandate of Congress under
12 such Act.

13 (3) The de novo process, created by the Food
14 and Drug Administration Modernization Act of 1997
15 (Public Law 105–115), is an approval mechanism by
16 which the Food and Drug Administration may
17 down-classify, to class I or class II, devices that have
18 no predicates and thus are designated class III, but
19 are deemed to be of low to moderate risk. The proc-
20 ess avoids having novel, low- to moderate-risk de-
21 vices go through the premarket approval process.
22 Under the current de novo process, the manufac-
23 turer must first make a submission under section
24 510(k) of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 360), even if no known predicate de-
26 vice exists. A 2011 Institute of Medicine report

1 found that, between 2005 and 2009, review times
2 for novel therapeutic devices through the de novo
3 process nearly tripled. The report concluded that the
4 current de novo process has not met its potential as
5 an alternative regulatory pathway, and recommended
6 the establishment of a modified de novo process.

7 **SEC. 3. ESTABLISHMENT OF SCHEDULE AND PROMULGA-**
8 **TION OF REGULATION.**

9 (a) ESTABLISHMENT OF SCHEDULE.—Not later than
10 120 days after the date of enactment of this Act, the Sec-
11 retary of Health and Human Services (referred to in this
12 section as the “Secretary”), shall establish the schedule
13 referred to in section 515(i)(3) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 360e(i)(3)) for each device
15 that the Secretary requires to remain in class III through
16 a determination under section 515(i)(2) of such Act.

17 (b) ACTION REGARDING CLASS II AND III.—Not
18 later than 18 months after the date of enactment of this
19 Act, the Secretary shall—

20 (1) issue a final regulation under section 515(b)
21 of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 360e(b)) for each device that the Secretary
23 requires to remain in class III through a determina-
24 tion under section 515(i)(2) of such Act; and

1 (2) establish the special controls required by
 2 section 513(a)(1)(B) of such Act (21 U.S.C.
 3 360c(a)(1)(B)) for each device that is classified into
 4 class II pursuant to a determination revising the
 5 classification of the device under section 515(i)(2) of
 6 such Act.

7 **SEC. 4. MODIFICATION OF DE NOVO APPLICATION PROC-**
 8 **ESS.**

9 (a) IN GENERAL.—Section 513(f)(2) of the Federal
 10 Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)) is
 11 amended—

12 (1) by redesignating subparagraphs (B) and
 13 (C) as subparagraphs (C) and (D), respectively;

14 (2) by amending subparagraph (A) to read as
 15 follows:

16 “(A) In the case of a type of device that has not pre-
 17 viously been classified under this Act, a person may do
 18 one of the following:

19 “(i) Submit a report under section 510(k), and,
 20 if the device is classified into class III under para-
 21 graph (1), such person may request, not later than
 22 30 days after receiving written notice of such a clas-
 23 sification, the Secretary to classify the device under
 24 the criteria set forth in subparagraphs (A) through
 25 (C) of subsection (a)(1). The person may, in the re-

1 quest, recommend to the Secretary a classification
2 for the device. Any such request shall describe the
3 device and provide detailed information and reasons
4 for the recommended classification.

5 “(ii) Submit a request for initial classification
6 of the device under this subparagraph, if the person
7 declares that there is no legally marketed device
8 upon which to base a substantial equivalence deter-
9 mination as that term is defined in section 513(i).
10 Subject to subparagraph (B), the Secretary shall
11 classify the device under the criteria set forth in sub-
12 paragraphs (A) through (C) of subsection (a)(1).
13 The person submitting the request for classification
14 under this subparagraph may recommend to the
15 Secretary a classification for the device and shall in-
16 clude in the request an initial draft proposal for ap-
17 plicable special controls, as described in subsection
18 (a)(1)(B), that are necessary, in conjunction with
19 general controls, to provide reasonable assurance of
20 safety and effectiveness and a description of how the
21 special controls provide such assurance.”;

22 (3) by inserting after subparagraph (A) the fol-
23 lowing:

24 “(B) The Secretary may decline to undertake a clas-
25 sification request submitted under clause (2)(A)(ii) if the

1 Secretary identifies a legally marketed device that could
 2 provide a reasonable basis for review of substantial equiva-
 3 lence under paragraph (1), or when the Secretary deter-
 4 mines that the device submitted is not of low-moderate
 5 risk.”; and

6 (4) in subparagraph (C), as so redesignated—

7 (A) in clause (i), by striking “Not later
 8 than 60 days after the date of the submission
 9 of the request under subparagraph (A),” and
 10 inserting “Not later than 90 days after the date
 11 of the submission of the request under subpara-
 12 graph (A)(i) or 120 days after the date of the
 13 submission of the request under subparagraph
 14 (A)(ii),”; and

15 (B) in clause (ii), by inserting “or is classi-
 16 fied in” after “remains in”.

17 (b) GAO REPORT.—Not later than 2 years after the
 18 date of enactment of this Act, the Comptroller General
 19 of the United States shall complete a study and submit
 20 to Congress a report on the effectiveness of the review
 21 pathway under section 513(f)(2)(A) of the Federal Food,
 22 Drug, and Cosmetic Act, as amended by this Act.

23 (c) CONFORMING AMENDMENT.—Section
 24 513(f)(1)(B) of the Federal Food, Drug, and Cosmetic

- 1 Act (21 U.S.C. 360c(f)(1)(B)) is amended by inserting “a
- 2 request under paragraph (2) or” after “response to”.

