

112TH CONGRESS
1ST SESSION

S. 1943

To amend section 513 of the Federal Food, Drug, and Cosmetic Act to expedite the process for requesting de novo classification of a device.

IN THE SENATE OF THE UNITED STATES

DECEMBER 5, 2011

Mr. BROWN of Massachusetts (for himself and Ms. AYOTTE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend section 513 of the Federal Food, Drug, and Cosmetic Act to expedite the process for requesting de novo classification of a device.

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.**

4 This Act may be cited as the “Novel Device Regu-
5 latory Relief Act of 2011”.

6 **SEC. 2. MODIFICATION OF DE NOVO APPLICATION PROC-**

7 **ESS.**

8 (a) IN GENERAL.—

1 (1) DE NOVO CLASSIFICATION.—Section
2 513(f)(2)(A) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360e(f)(2)(A)) is amended—

4 (A) by striking “(A) Any person” and in-
5 serting “(A)(i) Any person”; and

6 (B) by inserting after “classification.” the
7 following:

8 “(ii) A person may submit a request under clause (i)
9 without regard to whether such person has received writ-
10 ten notice of classification into class III under paragraph
11 (1).”.

12 (2) OPTION FOR INITIAL CLASSIFICATION.—
13 Section 513(f)(2) of the Federal Food, Drug, and
14 Cosmetic Act (22 U.S.C. 360e(f)(2)) is amended—

15 (A) by redesignating subparagraph (C) as
16 subparagraph (D); and

17 (B) by inserting after subparagraph (B)
18 the following:

19 “(C)(i) Any person that is required to submit a report
20 under section 510(k) with respect to a device, and deter-
21 mines that there is no legally marketed device upon which
22 to base a determination of substantial equivalence (as such
23 term is defined in subsection (i)), may submit a request
24 for initial classification of the device under this subpara-
25 graph. Subject to clause (ii), the Secretary shall classify

1 the device under the criteria set forth in subparagraphs
2 (A) through (C) of subsection (a)(1). The person submit-
3 ting the request for classification under this subparagraph
4 may recommend to the Secretary a classification for the
5 device.

6 “(ii) The Secretary may decline to undertake a classi-
7 fication request submitted under clause (i) when the Sec-
8 retary identifies a legally marketed device that would per-
9 mit a determination of substantial equivalence under para-
10 graph (1).”.

11 (b) CONFORMING AMENDMENT.—Section 513(f)(1)
12 of such Act (21 U.S.C. 360c(f)(1)) is amended—

13 (1) in subparagraph (A), by striking “or” at
14 the end;

15 (2) in subparagraph (B), by striking the period
16 and inserting “; or”; and

17 (3) by inserting after subparagraph (B) the fol-
18 lowing:

19 “(C) the device is classified pursuant to a
20 request submitted under paragraph (2).”.

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