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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Novel Device Regulatory Relief Act of 2011''.

SEC. 2. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) IN GENERAL.—

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

(A) by striking ''(A) Any person'' and inserting ''(A)(i) Any person''; and

(B) by inserting after ''classification.'' the following:

''(ii) A person may submit a request under clause (i) without regard to whether such person has received written notice of classification into class III under paragraph (1).''.

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

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

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

''(C)(i) Any person that is required to submit a report under section 510(k) with respect to a device, and determines that there is no legally marketed device upon which to base a determination of substantial equivalence (as such term is defined in subsection (i)), may submit a request for initial classification of the device under this subparagraph. Subject to clause (ii), the Secretary shall classify

the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device.

''(ii) The Secretary may decline to undertake a classification request submitted under clause (i) when the Secretary identifies a legally marketed device that would permit a determination of substantial equivalence under paragraph (1).''.

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

(1) in subparagraph (A), by striking ''or'' at the end;

(2) in subparagraph (B), by striking the period and inserting ''; or''; and

(3) by inserting after subparagraph (B) the following:

''(C) the device is classified pursuant to a request submitted under paragraph (2).''.

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