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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

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 HOUSE OF REPRESENTATIVES

Mr. BILBRAY (for himself, Mrs. BLACKBURN, Mr. LANCE, Mr. BURGESS, Mr. PAULSEN, and Mrs. CAPPS) introduced the following bill; which was referred to the Committee on _____

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

(1) by striking '' (A) Any person'' and all that follows through ''to classify'' and inserting ''(A)(i) Any person introducing or delivering for introduction into interstate commerce for commercial distribution a device intended for human use may request that the Secretary classify''; and

(2) 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).''.

(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).''.