

112TH CONGRESS  
1ST SESSION

# H. R. 3203

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

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mr. BILBRAY (for himself, Mrs. BLACKBURN, Mr. LANCE, Mr. BURGESS, Mr. PAULSEN, Mrs. CAPPES, Mr. GUTHRIE, Mr. HUNTER, Mr. DENT, Mr. STEARNS, Mr. LATTA, and Mr. SHIMKUS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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”.

1 **SEC. 2. MODIFICATION OF DE NOVO APPLICATION PROC-**  
2 **ESS.**

3 (a) IN GENERAL.—Section 513(f)(2)(A) of the Fed-  
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
5 360c(f)(2)(A)) is amended—

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

12 (2) by inserting after “classification.” the fol-  
13 lowing:

14 “(ii) A person may submit a request under clause (i)  
15 without regard to whether such person has received writ-  
16 ten notice of classification into class III under paragraph  
17 (1).”.

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

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

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

24 (3) by inserting after subparagraph (B) the fol-  
25 lowing:

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

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