

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 2193

To require the Food and Drug Administration to include devices in the postmarket risk identification and analysis system, to expedite the implementation of the unique device identification system for medical devices, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MARCH 15, 2012

Mr. MERKLEY (for himself, Mr. GRASSLEY, Mr. BENNET, and Mr. KOHL) 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 require the Food and Drug Administration to include devices in the postmarket risk identification and analysis system, to expedite the implementation of the unique device identification system for medical devices, 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.**

4 This Act may be cited as the “Ensuring Safe Medical  
5 Devices for Patients”.

1 **SEC. 2. ACTIVE POSTMARKET RISK IDENTIFICATION AND**  
2 **ANALYSIS.**

3 (a) RECORDS AND REPORTS ON DEVICES.—Section  
4 519 of the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 360i) is amended by inserting after subsection (c)  
6 the following:

7 “(d) INCLUSION OF DEVICES IN THE POSTMARKET  
8 RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Not  
9 later than 90 days after the date of enactment of the En-  
10 suring Safe Medical Devices for Patients, the Secretary  
11 shall amend the procedures established and maintained  
12 under section 505(k)(3)(C) in order to expand the  
13 postmarket risk identification and analysis system estab-  
14 lished under such section to include and apply to devices  
15 in a comparable manner as such system includes and ap-  
16 plies to drugs. The Secretary shall ensure that such  
17 amendments to the procedures shall give priority for inclu-  
18 sion in the postmarket risk identification and analysis sys-  
19 tem to class III and class II devices that are implantable,  
20 life-supporting or life-sustaining, or pose significant risk  
21 to users.”.

22 (b) UNIQUE DEVICE IDENTIFICATION SYSTEM.—  
23 Section 519(f) of the Federal Food, Drug, and Cosmetic  
24 Act (21 U.S.C. 360i(f)) is amended—

1           (1) by striking “The Secretary shall promul-  
2           gate” and inserting “Not later than December 31,  
3           2012, the Secretary shall issue final”; and

4           (2) by adding at the end the following:

5           “The Secretary shall implement the unique device identi-  
6           fication system under this subsection not later than 1 year  
7           after the date on which the final regulations are issued.”.

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