

110TH CONGRESS  
2D SESSION

# S. 3398

To amend the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices.

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## IN THE SENATE OF THE UNITED STATES

JULY 31, 2008

Mr. REID (for Mr. KENNEDY (for himself, Mr. LEAHY, Mr. DODD, Mr. HARKIN, Ms. MIKULSKI, Mr. BINGAMAN, Mrs. MURRAY, Mr. REED, Mrs. CLINTON, Mr. OBAMA, Mr. SANDERS, Mr. BROWN, and Mr. WHITEHOUSE)) 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 the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices.

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 “Medical Device Safety  
5 Act of 2008”.

1 **SEC. 2. LIABILITY UNDER STATE AND LOCAL REQUIRE-**  
2 **MENTS RESPECTING DEVICES.**

3 (a) AMENDMENT.—Section 521 of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by  
5 adding at the end the following:

6 “(c) NO EFFECT ON LIABILITY UNDER STATE  
7 LAW.—Nothing in this section shall be construed to mod-  
8 ify or otherwise affect any action for damages or the liabil-  
9 ity of any person under the law of any State.”.

10 (b) EFFECTIVE DATE; APPLICABILITY.—The amend-  
11 ment made by subsection (a) shall—

12 (1) take effect as if included in the enactment  
13 of the Medical Device Amendments of 1976 (Public  
14 Law 94–295); and

15 (2) apply to any civil action pending or filed on  
16 or after the date of enactment of this Act.

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