

114TH CONGRESS
2D SESSION

S. 2503

To establish requirements for reusable medical devices relating to cleaning instructions and validation data, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2016

Mrs. MURRAY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish requirements for reusable medical devices relating to cleaning instructions and validation data, 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 “Preventing Superbugs
5 and Protecting Patients Act”.

6 **SEC. 2. CLEANING INSTRUCTIONS AND VALIDATION DATA**
7 **REQUIREMENT.**

8 Section 510 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 360) is amended by adding at the end the
10 following:

1 “(q)(1) REUSABLE MEDICAL DEVICES.—Not later
2 than 6 months after the date of enactment of this sub-
3 section, the Secretary shall identify and publish a list of
4 reusable devices or types of devices for which reports
5 under subsection (k) must include proposed labeling, in-
6 cluding instructions for use, which have been validated in
7 a manner specified by the Secretary, and validation data,
8 the types of which shall be specified by the Secretary, re-
9 garding cleaning, disinfection, and sterilization, and for
10 which a substantial equivalence determination may be
11 based.

12 “(2) The Secretary shall revise such list as necessary
13 with notice in the Federal Register.

14 “(3) Reports under subsection (k) that are submitted
15 after the publication of the list described in paragraph (1),
16 for devices or types of devices included on such list, are
17 required to include such labeling and validation data.”.

18 **SEC. 3. DEVICE MODIFICATIONS.**

19 The Secretary shall issue final guidance regarding
20 when a premarket notification under section 510(k) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k))
22 is required to be submitted for a modification or change
23 to a legally marketed device not later than 1 year after

- 1 the date on which the comment period closes for the draft
- 2 guidance on such subject.

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