

114TH CONGRESS
2D SESSION

H. R. 4966

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 15, 2016

Mr. TED LIEU of California (for himself and Mr. ROSKAM) introduced the following bill; which was referred to the Committee on Energy and Commerce

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) REUSABLE MEDICAL DEVICES.—(1) 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 device types for which reports under subsection
5 (k) must include instructions for use, which have been
6 validated in a manner specified by the Secretary, and vali-
7 dation data, the types of which shall be specified by the
8 Secretary, regarding cleaning, disinfection, and steriliza-
9 tion, and for which a substantial equivalence determina-
10 tion may be based.

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

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

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

19 The Secretary of Health and Human Services, acting
20 through the Commissioner of Food and Drugs, shall issue
21 final guidance regarding when a premarket notification
22 under section 510(k) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 360(k)) is required to be submitted
24 for a modification or change to a legally marketed device

- 1 not later than 1 year after the date on which the comment
- 2 period closes for the draft guidance on such subject.

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