115TH CONGRESS
1ST SESSION

S. 1070

To amend the Federal Food, Drug, and Cosmetic Act to provide for the appropriate, risk-based classification of device accessories based on intended use.

IN THE SENATE OF THE UNITED STATES

MAY 8, 2017

Mr. ROBERTS (for himself, Mr. DONNELLY, and Mr. BURR) 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 to provide for the appropriate, risk-based classification of device accessories based on intended use.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Realizing Intended Safety for Certain Accessories Act of 2017''.

SEC. 2. RISK-BASED CLASSIFICATION OF ACCESSORIES.

Section 513(b)(9) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(9)) is amended—

(1) by striking ''(9) The Secretary'' and inserting ''(9)(A) The Secretary''; and

(2) by adding at the end the following:

''(B) The classification of any accessory classified prior to December 13, 2016, based on the intended use or uses of such accessory, shall continue to apply, notwithstanding the classification of any other device with which such accessory is intended to be used.

''(C)(i) If—

''(I) an accessory has been cleared or approved based on the classification of another device with which such accessory is intended to be used; and

''(II) the Secretary has established a classification for such accessory based on the intended use or uses of the accessory, in accordance with subparagraph (A),

the manufacturer of such accessory may identify the classification described in subclause (II) in a written notification to the Secretary.

''(ii) Unless the Secretary notifies a manufacturer within 30 calendar days of receipt of a written notification described in clause (i) that the Secretary does not agree that the classification identified in such written notification is appropriate for the accessory, the accessory shall

be automatically reclassified in accordance with the classification identified in such written notification.

''(iii) A written notification that the Secretary disagrees with the classification identified in a written notification described in clause (ii) shall include a detailed description and justification for the determination to disagree.

''(D)(i) A manufacturer of an accessory that has been previously classified by the Secretary based on the intended use of another device with which the accessory is intended to be used, through an application for such other device under section 515(c), a report under section 510(k), or a petition for classification under section 513(f)(2), and that has not been classified by the Secretary based on the intended use or uses of the accessory as described in subparagraph (A) or (C), may submit to the Secretary a written recommendation for the appropriate classification of such accessory based on its intended use or uses. Such submission shall include such information to support the recommendation as the Secretary may require.

''(ii) The Secretary shall respond to a submission under clause (i) within 60 calendar days by approving or denying the recommended classification of the accessory. If the Secretary does not agree with the recommendation for classification submitted by the sponsor, the response

shall include a detailed description and justification for such determination to disagree. The Secretary shall provide an opportunity for a manufacturer to meet with appropriate personnel to discuss appropriate classification of such accessory prior to submitting a written recommendation.

''(E) At the time a sponsor submits an application for premarket approval for a class III device pursuant to section 515(c), the sponsor of such application may include a recommendation and supporting information for the proper classification of such accessory pursuant to subparagraph (A). If such device is intended to be used with an accessory that has not been classified by the Secretary based on its intended use or uses as described in subparagraph (A) or (C), the Secretary shall—

''(i) approve or deny the application pursuant to section 515(d); and

''(ii) approve or deny the classification of the accessory proposed in the application submitted under this clause.

''(F) A manufacturer may at any time use the classification process described in section 513(f)(2) to obtain classification of an accessory.''.

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