S 2737

Improving Medical Device Innovation Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 17, 2016
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 17, 2016)
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Sponsor

Name: Sen. Klobuchar, Amy [D-MN]
Party: Democratic • **State:** MN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Roberts, Pat [R-KS]	R · KS		Mar 17, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 17, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 2425	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2426	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2427	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.

Summary (as of Mar 17, 2016)

Improving Medical Device Innovation Act

This bill amends the Federal Food, Drug, and Cosmetic Act to revise provisions related to medical device performance standards, reporting requirements, and classification panels.

A person may request that the Food and Drug Administration (FDA) recognize a performance standard established by a recognized standards organization as a standard to which a medical device may conform in order to meet an FDA requirement. When a request to recognize a standard is received, the FDA must determine whether to recognize all, part, or none of the standard and publish the rationale for that determination. (Currently, the FDA recognizes certain performance standards, but it is not required to respond to requests or publish rationales.)

The FDA must:

- train employees who review premarket submissions for medical devices on recognized standards;
- review its published principles for recognizing standards;
- identify types of medical devices for which a premarket report is no longer needed to provide reasonable assurance of safety and effectiveness;
- ensure that adequate expertise is represented on medical device classification panels;
- provide an opportunity for a person whose premarket submission is subject to review by a classification panel to recommend expertise needed on the panel; and
- provide opportunities for patients, patient representatives, and medical device sponsors to recommend individuals for positions on classification panels.

The FDA, in coordination with medical device manufacturers, must establish pilot projects to evaluate alternative methods of compliance with reporting requirements for certain medical devices. The Government Accountability Office must report on these pilot projects.

Actions Timeline

- **Mar 17, 2016:** Introduced in Senate
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