S 1700

Medical Device Regulatory Improvement Act

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Oct 13, 2011
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. (Oct 13, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/1700

Sponsor

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

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		Oct 13, 2011
Sen. Burr, Richard [R-NC]	R · NC		Oct 13, 2011
Sen. Coburn, Tom [R-OK]	R · OK		Mar 22, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 13, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 13, 2011)

Medical Device Regulatory Improvement Act - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services (HHS), in determining the least burdensome appropriate means of evaluating device effectiveness, to: (1) not request information unrelated or irrelevant to demonstration of reasonable assurance of device safety and effectiveness; (2) consider alternative approaches to evaluating device safety and effectiveness; (3) use all reasonable mechanisms to lessen review times and render regulatory decisions; (4) determine whether pre-clinical data can meet the statutory threshold for approval; and (5) utilize, whenever practicable, alternatives to randomized, controlled clinical trials if clinical data are needed.

Requires the Secretary, in determining the least burdensome means of determining substantial equivalence, to: (1) focus on whether the device has the same intended use as the predicate device and is as safe and effective as a legally marketed device, (2) not request or accept information unrelated or irrelevant to the substantial equivalence evaluation, (3) review the labeling of the device to assess the intended use of the device and not evaluate issues that do not present a major impact on the intended use as set forth in the labeling, (4) consider alternative approaches to evaluating substantial equivalence, and (5) use all reasonable mechanisms to lessen review times and render regulatory decisions.

Repeals conflict-of-interest provisions that are specific to the Food and Drug Administration (FDA) and provides for the continued applicability of conflict-of-interest provisions otherwise applicable to advisory committees, federal employees, and special government employees.

Requires the Secretary to contract with an eligible entity for a review of the management and regulatory processes at the Center for Devices and Radiological Health.

Actions Timeline

- **Oct 13, 2011:** Introduced in Senate
- **Oct 13, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.