HR 3847

SOUND Devices Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Jan 31, 2012
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (Jan 31, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/3847

Sponsor

Name: Rep. Markey, Edward J. [D-MA-7]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeLauro, Rosa L. [D-CT-3]	D · CT		Jan 31, 2012
Rep. Schakowsky, Janice D. [D-IL-9]	D · IL		Jan 31, 2012
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Jan 31, 2012
Rep. Slaughter, Louise McIntosh [D-NY-28]	D · NY		Feb 29, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Jan 31, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jan 31, 2012)

Safety Of Untested and New Devices Act of 2012 or the SOUND Devices Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to require a medical device company seeking approval of a new device based on a determination of substantial equivalence to a predicate device to inform the Food and Drug Administration (FDA) if any predicate lineage products have harmed device recipients and to explain how the current device avoids past flaws.

Prohibits finding a new device substantially equivalent to a predicate device if the predicate has been removed from the market by the Secretary of Health and Human Services (HHS) or determined to be misbranded or adulterated by judicial order.

Permits the FDA to reject a claim of substantial equivalency for a device whose predicate has been corrected or removed from the market by its sponsor.

Requires the Secretary to maintain an up-to-date database for purposes of determining whether devices are eligible for use as a predicate device.

Requires each manufacturer's corrective action or removal of device report to contain the root cause of each defect leading to the corrective action or removal.

Requires a manufacturer's report for devices in the same lineage as devices that have been subject to corrections or removals and requires such report to explain why the subsequent device does not share the flaws of its predecessor device.

Requires the Secretary to conduct a review of all covered devices to identify any such devices with respect to which a predicate device, or any device in the full device lineage, has been corrected or removed from the market pursuant to a Class I or Class II recall.

Actions Timeline

- **Jan 31, 2012:** Introduced in House
- **Jan 31, 2012:** Referred to the House Committee on Energy and Commerce.