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Novel Device Regulatory Relief Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Dec 5, 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. (Dec 5, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/1943

Sponsor

Name: Sen. Brown, Scott P. [R-MA]
Party: Republican • **State:** MA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Ayotte, Kelly [R-NH]	R · NH		Dec 5, 2011

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 5, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Dec 5, 2011)

Novel Device Regulatory Relief Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act to allow a person to request the Secretary of Health and Human Services (HHS) to classify a device regardless of whether the person has received written notice of classification into class III (premarket approval) under the initial classification procedures applicable to devices introduced or delivered for introduction into interstate commerce before May 28, 1976.

Allows a person that is required to submit a report preceding the introduction of device into interstate commerce, and determines that there is no legally marketed device upon which to base a determination of substantial equivalence, to request an initial classification of the device and to recommend to the Secretary a classification. Allows the Secretary to decline to undertake such a request when the Secretary identifies a legally marketed device that would permit a determination of substantial equivalence.

Actions Timeline

- **Dec 5, 2011:** Introduced in Senate
- **Dec 5, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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