HR 818

DEVICE Act of 2019

Congress: 116 (2019–2021, Ended)
Chamber: House
Policy Area: Health
Introduced: Jan 28, 2019
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jan 29, 2019)
Official Text: https://www.congress.gov/bill/116th-congress/house-bill/818

Sponsor

Name: Rep. Lieu, Ted [D-CA-33]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		Jan 28, 2019
Rep. Chu, Judy [D-CA-27]	D · CA		Jan 28, 2019
Rep. Cummings, Elijah E. [D-MD-7]	D · MD		Jan 28, 2019
Rep. Grijalva, Raúl M. [D-AZ-3]	D · AZ		Jan 28, 2019

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jan 29, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jan 28, 2019)

Disclosure; and Encouragement of Verification, Innovation, Cleaning, and Efficiency Act of 2019 or the DEVICE Act of 2019

This bill addresses design changes and reprocessing of medical devices. Reprocessing of medical devices is the process to clean and sterilize or disinfect devices for reuse. Specifically, medical device manufacturers must notify the Food and Drug Administration (FDA) (1) before making changes to the design or reprocessing instructions of a device, and (2) no more than five days after widely disseminating to health care providers in a foreign country communications regarding changes to the design or reprocessing instructions of a device or regarding a safety concern about a device. A device may not be sold if the manufacturer violates these notification requirements.

Rapid assessment tests intended to ensure the proper reprocessing of reusable medical devices are defined as medical devices. The FDA must publish a list of the types of rapid assessment tests for which premarket notification must include validated instructions for use and validation data.

Actions Timeline

- **Jan 29, 2019:** Referred to the Subcommittee on Health.
- **Jan 28, 2019:** Introduced in House
- **Jan 28, 2019:** Referred to the House Committee on Energy and Commerce.