

S 4386

A bill to allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan.

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jun 13, 2022

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. (Jun 13, 2022)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/4386>

Sponsor

Name: Sen. Braun, Mike [R-IN]

Party: Republican • **State:** IN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Hickenlooper, John W. [D-CO]	D · CO		Jun 13, 2022

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jun 13, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HR 8299	Identical bill	Jul 7, 2022: Referred to the House Committee on Energy and Commerce.

Summary (as of Jun 13, 2022)

This bill allows changes to be made to medical devices without the need for supplemental applications or premarket notifications if the changes are made in accordance with a predetermined change control plan.

Actions Timeline

- **Jun 13, 2022:** Introduced in Senate
- **Jun 13, 2022:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.