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# 21 U.S. Code § 360e-4

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## Predetermined change control plans for devices

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### **(a) Approved devices**

#### **(1) In general**

Notwithstanding section 360e(d)(5)(A) of this title, a supplemental application shall not be required for a change to a device approved under section 360e of this title, if such change is consistent with a predetermined change control plan that is approved pursuant to paragraph (2).

#### **(2) Predetermined change control plan**

The Secretary may approve a predetermined change control plan submitted in an application, including a supplemental application, under section 360e of this title that describes planned changes that may be made to the device (and that would otherwise require a supplemental application under section 360e of this title), if the device remains safe and effective without any change.

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