

117TH CONGRESS
2D SESSION

S. 4386

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.

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2022

Mr. BRAUN (for himself and Mr. HICKENLOOPER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. PREDETERMINED CHANGE CONTROL PLANS**
4 **FOR DEVICES.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
7 ed by inserting after section 515B (21 U.S.C. 360e–3) the
8 following:

1 **“SEC. 515C. PREDETERMINED CHANGE CONTROL PLANS**
2 **FOR DEVICES.**

3 “(a) APPROVED DEVICES.—

4 “(1) IN GENERAL.—Notwithstanding section
5 515(d)(5)(A), a supplemental application shall not
6 be required for a change to a device approved under
7 section 515, if such change is consistent with a pre-
8 determined change control plan that is approved
9 pursuant to paragraph (2).

10 “(2) PREDETERMINED CHANGE CONTROL
11 PLAN.—The Secretary may approve a predetermined
12 change control plan submitted in an application, in-
13 cluding a supplemental application, under section
14 515 that describes planned changes that may be
15 made to the device (and that would otherwise re-
16 quire a supplemental application under section 515),
17 if the device remains safe and effective without any
18 change.

19 “(3) SCOPE.—The Secretary may require that a
20 change control plan include labeling required for
21 safe and effective use of the device as such device
22 changes pursuant to such plan, notification require-
23 ments if the device does not function as intended
24 pursuant to such plan, and performance require-
25 ments for changes made under the plan.

26 “(b) CLEARED DEVICES.—

1 “(1) IN GENERAL.—Notwithstanding section
2 510(k), a premarket notification shall not be re-
3 quired for a change to a device cleared under section
4 510(k), if such change is consistent with an estab-
5 lished predetermined change control plan granted
6 pursuant to paragraph (2).

7 “(2) PREDETERMINED CHANGE CONTROL
8 PLAN.—The Secretary may clear a predetermined
9 change control plan submitted in a notification sub-
10 mitted under section 510(k) that describes planned
11 changes that may be made to the device (and that
12 would otherwise require a new notification), if—

13 “(A) the device remains safe and effective
14 without any such change; and

15 “(B) the device would remain substantially
16 equivalent to the predicate.

17 “(3) SCOPE.—The Secretary may require that a
18 change control plan include labeling required for
19 safe and effective use of the device as such device
20 changes pursuant to such plan, notification require-
21 ments if the device does not function as intended
22 pursuant to such plan, and performance require-
23 ments for changes made under the plan.

24 “(c) PREDICATE DEVICES.—In making a determina-
25 tion of substantial equivalence pursuant to section 513(i),

1 the Secretary shall not compare a device to changed
 2 versions of a device implemented in accordance with an
 3 established predetermined change control plan as a predi-
 4 cate device. Only the version of the device cleared or ap-
 5 proved, prior to changes made under the predetermined
 6 change control plan, may be used by a sponsor as a predi-
 7 cate device.”.

8 (b) CONFORMING AMENDMENTS.—

9 (1) CLEARED DEVICES.—Section 510(l)(1) of
 10 the Federal Food, Drug, and Cosmetic Act (21
 11 U.S.C. 360(l)(1)) is amended, in the first sentence,
 12 by inserting “, or with respect to a change that is
 13 consistent with a predetermined change control plan
 14 cleared under section 515C” before the period at the
 15 end.

16 (2) APPROVED DEVICES.—Section
 17 515(d)(5)(A)(i) of the Federal Food, Drug, and Cos-
 18 metic Act (21 U.S.C. 360e(d)(5)(A)(i)) is amended
 19 by striking “A supplemental” and inserting “Unless
 20 the change is consistent with a predetermined
 21 change control plan approved under section 515C, a
 22 supplemental”.

23 (3) DOCUMENTATION OF RATIONALE FOR SIG-
 24 NIFICANT DECISIONS.—Section 517A(a)(1) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 360g–1(a)(1)) is amended to read as follows:

3 “(1) IN GENERAL.—The Secretary shall provide
4 a substantive summary of the scientific and regu-
5 latory rationale for any significant decision of the
6 Center for Devices and Radiological Health regard-
7 ing submission or review of a report under section
8 510(k), a petition for classification under section
9 513(f), an application under section 515, or an ap-
10 plication for an exemption under section 520(g), in-
11 cluding documentation of significant controversies or
12 differences of opinion and the resolution of such con-
13 troversies or differences of opinion.”.

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