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117TH CONGRESS
2D SESSION

H. R. 8299

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 HOUSE OF REPRESENTATIVES

JULY 7, 2022

Mr. BILIRAKIS (for himself and Mr. O'HALLERAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PREDETERMINED CHANGE CONTROL PLANS FOR DEVICES.

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

"SEC. 515C. PREDETERMINED CHANGE CONTROL PLANS FOR DEVICES.

''(a) APPROVED DEVICES.—

''(1) IN GENERAL.—Notwithstanding section 515(d)(5)(A), a supplemental application shall not be required for a change to a device approved under section 515, 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 515 that describes planned changes that may be made to the device (and that would otherwise require a supplemental application under section 515), if the device remains safe and effective without any change.

''(3) SCOPE.—The Secretary may require that a change control plan include labeling required for safe and effective use of the device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan.

''(b) CLEARED DEVICES.—

''(1) IN GENERAL.—Notwithstanding section 510(k), a premarket notification shall not be required for a change to a device cleared under section 510(k), if such change is consistent with an established predetermined change control plan granted pursuant to paragraph (2).

''(2) PREDETERMINED CHANGE CONTROL PLAN.—The Secretary may clear a predetermined change control plan submitted in a notification submitted under section 510(k) that describes planned changes that may be made to the device (and that would otherwise require a new notification), if—

''(A) the device remains safe and effective without any such change; and

''(B) the device would remain substantially equivalent to the predicate.

''(3) SCOPE.—The Secretary may require that a change control plan include labeling required for safe and effective use of the device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan.

''(c) PREDICATE DEVICES.—In making a determination of substantial equivalence pursuant to section 513(i),

the Secretary shall not compare a device to changed versions of a device implemented in accordance with an established predetermined change control plan as a predicate device. Only the version of the device cleared or approved, prior to changes made under the predetermined change control plan, may be used by a sponsor as a predicate device.''.

(b) CONFORMING AMENDMENTS.—

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

(2) APPROVED DEVICES.—Section 515(d)(5)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(i)) is amended by striking ''A supplemental'' and inserting ''Unless the change is consistent with a predetermined change control plan approved under section 515C, a supplemental''.

(3) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—Section 517A(a)(1) of the

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

''(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), a petition for classification under section 513(f), an application under section 515, or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.''.

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