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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-Z-0025]

Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements; Withdrawal of Proposed Exemptions

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice of withdrawal.

SUMMARY: The Department of Health and Human Services (HHS or "The Department") issued a Notice in the *Federal Register* of January 15, 2021, that, among other things, proposed to exempt 83 class II devices and 1 unclassified device from premarket notification. This Notice announces HHS's and the Food and Drug Administration's (FDA or "the Agency") withdrawal of the proposed exemptions for the 83 class II devices and 1 unclassified device. The comment period for the proposed class II and unclassified device exemptions closed on March 15, 2021. HHS and FDA are withdrawing the proposed exemptions after reviewing the Notice, its comments, inquiries to FDA, and other relevant information, and determining that the proposed exemptions and bases for them are flawed.

DATES: The proposed exemptions of 83 class II devices and 1 unclassified device, published on January 15, 2021 (86 FR 4088), are withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Angela Krueger, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1660, Silver Spring, MD 20993, 301-796-6380, or by email at RPG@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 ("1976 amendments") (Pub. L. 94-295), and the Safe Medical Devices Act of 1990 (Pub. L. 101-629), devices are classified into class I ("general controls") if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II ("special controls"), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic device types that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as "preamendments devices") have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as "postamendments devices"), are generally classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations in 21 CFR part 807 require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially

equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

Section 510(m)(2) of the FD&C Act allows FDA, on its own initiative or in response to an exemption petition, to issue in the *Federal Register* a notice of intent to exempt any type of class II device from the requirement to submit a report under section 510(k) of the FD&C Act, if the Agency determines that such a report is not necessary to assure the safety and effectiveness of the device. Section 510(m)(2) further provides that the public may comment on FDA's proposed exemptions for 60 days after publication in the *Federal Register* and that FDA shall issue an order setting forth the final determination within 120 days.

In addition, section 510(m)(1)(A) of the FD&C Act requires FDA to, within 90 days after enactment in December 2016 and at least once every 5 years, publish a list of each type of class II device that FDA determines no longer requires a report under section 510(k) to provide a reasonable assurance of safety and effectiveness, along with a public comment period of at least 60 days. Section 510(m)(3) provides that, upon publication of the final list in the *Federal Register*, each type of class II device listed shall be exempt from the requirement for a report under section 510(k), and the classification regulation applicable to each type of device shall be deemed amended to incorporate such exemption. In accordance with these statutory requirements, FDA published a notice of proposed class II exemptions in the *Federal Register* on March 14, 2017 (82 FR 13609), and a final list of its class II exemptions on July 11, 2017 (82 FR 31976).

II. Criteria for Exemption from Section 510(k) of the FD&C Act

Section 510(m)(2) of the FD&C Act permits FDA to exempt class II devices from the premarket notification requirements of section 510(k), where the Agency has determined that such notification is not necessary to assure the safety and effectiveness of the device. To make that determination, FDA considers a number of factors, which the Agency first described in the January 21, 1998, *Federal Register* notice (63 FR 3142), and explained in FDA's guidance

issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff" (Class II 510(k) Exemption Guidance).[1] [2] As described in those documents, FDA generally considers the following factors to determine whether class II device types should be exempted from premarket notification: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification.

FDA may also consider that, even when exempting devices, these devices will still be subject to the limitations on exemptions. After considering these factors, FDA determines whether specific device types are appropriate for exemption from section 510(k) because a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. FDA has published several lists of class II device types exempted or proposed to be exempted from the premarket notification requirements of section 510(k), including on January 21, 1998 (63 FR 3142), March 14, 2017 (82 FR 13609), and July 11, 2017 (82 FR 31976). Since enactment of section 510(m) of the FD&C Act, each time that FDA has published a list of exemptions, it has reiterated the above criteria that it evaluates and has documented the determination that a 510(k) submission is not necessary to assure the safety and effectiveness of the device.

III. Limitations on Exemptions

[1] On January 21, 1998, to comply with the requirements of the Food and Drug Administration Modernization Act of 1997, FDA published a list of class II devices exempt from premarket notification. After the 21st Century Cures Act went into effect, in compliance with the requirement of section 510(m)(1)(A), FDA published a notice of proposed class II device type exemptions in the *Federal Register* on March 14, 2017 (82 FR 13609), and a final list of its class II exemptions on July 11, 2017 (82 FR 31976).

[2] The guidance for industry and Center for Devices and Radiological Health (CDRH) is available at https://www.fda.gov/files/medical%20devices/published/Procedures-for-Class-II-Device-Exemptions-from-Premarket-Notification--Guidance-for-Industry-and-CDRH-Staff-%28PDF-Version%29.pdf.

Exemptions to the premarket notification requirements of 510(k) apply only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type. General limitations to exemptions for class II devices are set forth in each of the device classification regulations (§§ 862.9 through 892.9 (21 CFR 862.9 through 892.9)). Thus, a manufacturer of an exempted device is still required to submit a premarket notification before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in §§ 862.9 through 892.9.

In addition, FDA may also partially limit an exemption within a listed device type, taking into account the factors described in the Class II 510(k) Exemption Guidance. For example, although FDA has granted an exemption under 510(m)(2) to certain optical position/movement recording systems, it limits that exemption to devices for prescription use only (85 FR 44186, July 22, 2020). In those situations, FDA determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for a subset of those devices of the listed device type.

The exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's determination that premarket notification is unnecessary to provide a reasonable assurance of safety and effectiveness for certain devices is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

IV. FDA's Enforcement Policy During the Public Health Emergency

FDA has issued guidance documents related to the Coronavirus Disease 2019 (COVID-19) public health emergency (COVID-19 PHE), some of which set forth enforcement policies intended to help expand the availability of certain devices by providing regulatory flexibility for

products that have already submitted premarket notification.[3] For each such enforcement policy, FDA has noted that it does not intend to object to certain modifications to these devices or their indications of use. For all of the guidance documents related to devices, FDA specifically limited the policies to the duration of the COVID-19 PHE.

In one such guidance, FDA's "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" (Ventilator Guidance), FDA stated its intention not to object to limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of class II FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior submission of a premarket notification under section 510(k), where the modification will not create an undue risk in light of the COVID-19 PHE.[4] In addition, FDA's Ventilator Guidance noted that FDA does not intend to object to changes in the indicated shelf life and duration of use of these products for treating individual patients, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the change does not create an undue risk in light of the COVID-19 PHE. FDA's Ventilator Guidance provided examples of circumstances where FDA currently believes these types of modifications would not create such an undue risk.

These enforcement policies are limited in scope and duration, and they communicate FDA's nonbinding views about how it should allocate its enforcement resources based on current facts and circumstances. Such policies do not alter the legal obligation to comply with the relevant requirements and do not preclude the Agency from taking action to enforce those requirements where appropriate. These particular enforcement policies were issued in response to a highly unusual set of facts and circumstances: the most sweeping PHE to occur in over a

[3] FDA's guidances related to the COVID-19 PHE are available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

[4] The policies set forth in the Ventilator Guidance apply to ventilators with the product codes CBK, MNT, NOU, NQY, MNS, ONZ, BTL, BSZ, BZD, NFB, NHJ, NHK, and QAV.

century. The public health threat caused by COVID-19, the disease caused by the SARS-CoV-2 virus, is substantial. Global demand for certain devices, such as ventilators, has increased significantly and is a critical part of the response to the COVID-19 outbreak. FDA's COVID-19 PHE guidance documents provide information, recommendations, and policies to help address the urgent need for certain devices and help expand the availability of those devices during the COVID-19 PHE.

V. The January 15, 2021, Notice and Reasons for Withdrawal

On January 15, 2021, HHS published a Notice (the "January 15, 2021, Notice") (86 FR 4088) proposing to exempt 83 class II device types and 1 unclassified device type from the 510(k) premarket notification requirements. We did not find any evidence that HHS consulted with, otherwise involved, or even notified FDA before issuing the Notice. Some of these proposed exemptions include device types that are indicated for a use in supporting or sustaining human life, such as product code NQY ("Ventilator, Continuous, Minimal Ventilatory Support, Home Use"). The determinations in the proposal were based solely on a tally of adverse events in FDA's Manufacturer and User Facility Device Experience database (MAUDE), and the conclusion was based on the number of adverse events MAUDE tabulated. The Notice stated that "[g]iven the lack of any adverse event reports in MAUDE for [certain of the] class II and the unclassified medical devices . . . and the lack of non-death-related [sic] adverse event reports for [certain other] class II devices . . . the Department has determined that 510(k) premarket notification for the 84 [sic] class II devices and the unclassified device . . . is no longer necessary to assure the safety and effectiveness of those devices." (86 FR 4088 at 4096). The January 15, 2021, Notice did not identify any limitations on any of the 84 proposed exemptions, nor did it indicate that HHS considered whether any such limitations were appropriate.

Upon review, HHS and FDA have determined that the proposed exemptions in the January 15, 2021, Notice were published without adequate scientific support, that the Notice contained errors and ambiguities, and that the Notice is otherwise flawed, as described below.

This review was prompted primarily by two things. One is that staff and leadership in FDA's Center for Devices and Radiological Health that conduct regulatory oversight of these products identified several issues described below and brought them to the Department's attention. The other is that HHS has received dozens of inquiries about the January 15, 2021, Notice, as part of comments on the Notice submitted to the docket as well as inquiries sent to the contact listed in that Notice, or to various FDA staff and FDA program email addresses. For example, there were many comments and inquiries asking about various potential errors and ambiguities, such as about mismatched product descriptions, product codes, and regulatory citations.

The January 15, 2021, Notice relied solely upon adverse event reports in MAUDE in determining that a 510(k) is no longer necessary to assure the safety and effectiveness of the devices. Although adverse event reports are a valuable source of information, the reports have limitations, as noted in the January 15, 2021, Notice, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from adverse event reports alone, due to underreporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. As noted by several commenters, reliance on adverse event reports in MAUDE is an inappropriate basis for exemption because, for example, adverse events may be underreported for certain devices, and a low number of reports in MAUDE may reflect the low number of marketed devices, and not necessarily the risk of injury. In addition, relying exclusively on MAUDE data leaves out other important information regarding risk. For example, FDA routinely considers recall information as part of its risk analyses, including for class II 510(k) exemptions.

Moreover, to exempt a device from 510(k) under the standard set forth in section 510(m)(2) of the FD&C Act, FDA must determine that a 510(k) submission is no longer necessary to assure the safety or effectiveness of the device. Not only is adverse event data inadequate on its own for assessing safety, it may provide little or no information about

effectiveness, for purposes of proposing exemptions. As some comments noted, inaccurate readings from certain devices, including tonometers, electrocardiographs, electroencephalographs, seizure monitoring systems, vestibular analysis apparatus, or cerebral oximeters may contribute to erroneous clinical and surgical decisions, but may not be reflected in MAUDE.

To the extent adverse event data is a relevant factor in determining whether to exempt a class II device type from premarket notification, the January 15, 2021, Notice reflects an improperly narrow consideration of the adverse event data. The Notice proposed to exempt 50 class II device types based solely on a lack of death-related adverse event reports available in MAUDE for the time period searched, while failing to consider adverse event reports submitted under other event types, including "injury" and "malfunction." In just one example, table 4.2 of the Notice states that for product code MOS (erroneously described as "Implanted Subcutaneous Securement Catheter"), there were zero MAUDE reports submitted under "death," but there were 73 other reports, including 13 submitted under "malfunction" and 52 under "injury." While adverse event data should not provide the sole basis for an exemption, FDA has considered all adverse event data relevant to its determinations and has not limited its consideration to only those adverse event reports submitted under the "death" event type. This is because, for example, device malfunctions or injuries that do not result in death still inform whether a 510(k) submission is necessary to assure the safety or effectiveness of the device. In addition, the event types in MAUDE are supplied by the submitter, and thus death-related adverse events may be mistakenly submitted under other event types, such as "Other," if any event type is specified at all.

In considering whether exemption from 510(k) is appropriate for class II device types, FDA has consistently taken into account both safety and effectiveness, and considers the factors identified in the January 21, 1998, FR notice (63 FR 3142), and as explained in FDA's guidance "Procedures for Class II Device Exemptions from Premarket Notification," including whether (1)

the device has had a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) any device characteristics necessary for its safe and effective performance are well established; (3) any changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. These factors are relevant to understanding whether a premarket notification is necessary to assure the safety and effectiveness of a device. FDA has consistently used them since 1998, when section 510(m) was first enacted. However, these factors were not considered as part of the January 15, 2021, Notice. As mentioned above, the January 15, 2021, Notice only considered one piece of information--MAUDE data--which is a drastically narrower approach to the evaluation of whether a device should be exempt than the factors FDA has consistently considered.

It was also an error for HHS to propose to exempt the unclassified device type with product code LXV from the premarket notification requirements. Unclassified devices require submission of a 510(k) premarket notification. The January 15, 2021, Notice proposes to exempt this unclassified device type from 510(k) under the process and standard of 510(m). Section 510(m), however, provides only for the exemption of class II devices. Unclassified devices are not class II devices. Therefore, 510(m) does not provide the standard or process for exemption of unclassified devices. The January 15, 2021, Notice did not cite to any other statutory provision that authorizes the exemption of unclassified devices from 510(k).

As noted, the January 15, 2021, Notice contained numerous errors and ambiguities, such as mismatched product descriptions, product codes, and regulatory citations. For example, table 6 in the Notice lists the 84 devices it proposed to exempt. One entry gives the Device description as "Oxygenator, Long Term Support Greater than 6 Hours," the Product code as "BZG," and the section in 21 CFR as "868.1840." The same table has a second listing for

"Oxygenator, Long Term Support Greater than 6 Hours," this one giving the Product code as "FXY" and the section in 21 CFR as "878.4040." However, "Oxygenator, Long Term Support Greater than 6 Hours" is Product code BYS and is classified in 21 CFR 870.4100. These errors and ambiguities make it difficult or impossible in some circumstances to discern which class II devices the Notice is proposing to exempt, as noted by some commenters.

Finally, we did not find evidence that HHS consulted with or otherwise involved FDA in its proposed exemption or the issuance of the January 15, 2021, Notice. Section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) provides that the Secretary "shall be responsible for executing" the FD&C Act "through the [FDA] Commissioner." Here, the January 15, 2021, Notice is clearly an action "executing" the FD&C Act. Moreover, it is particularly important that FDA have at least some level of involvement in this type of an action given the expertise needed in evaluating whether a submission under 510(k) of the FD&C Act is necessary to assure the safety and effectiveness of a device.

For these reasons, HHS and FDA are withdrawing the proposed exemptions of the 83 class II devices and 1 unclassified device published on January 15, 2021, at 86 FR 4088. Elsewhere in this issue of the *Federal Register*, HHS and FDA are stating their belief that the class I devices that are the subject of the January 15, 2021, Notice meet the criteria for reserved class I devices and that it is appropriate to reverse the determination of exemption for those devices.

Dated: April 12, 2021.

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Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: April 12, 2021.

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Xavier Becerra,

Secretary, Department of Health and Human Services.

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