4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2017-N-4919]

Medical Devices; Exemption from Premarket Notification: Class II Devices; Surgical Apparel; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to exempt certain subtypes of surgical apparel from premarket notification requirements, subject to conditions and limitations. FDA intends to limit the proposed exemption to single-use, disposable respiratory protective devices (RPD) used in a healthcare setting and worn by healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. These devices, commonly referred to as N95 filtering facepiece respirators (FFRs) and surgical N95 respirators (herein collectively referred to as N95s) are currently regulated by FDA under product code MSH. All other class II devices classified under FDA's surgical apparel classification regulation would continue to be subject to premarket notification requirements. FDA is publishing this document to obtain comments regarding this proposed exemption, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-4919 for "Medical Devices; Exemption From Premarket Notification: Class II Devices; Surgical Apparel; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets

Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aftin Ross, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301-796-5679, email: Aftin.Ross@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of 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 (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114-255) (Cures Act) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list under paragraph (1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the *Federal Register* notice of its intent to exempt the device, or of the petition, and provide a 60-calendar day period for public comment. Within 120 days after the issuance of the notice, FDA must publish an order in the *Federal Register* that sets forth its final determination regarding the exemption of the device that was the subject of the notice.

II. Factors FDA May Consider for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, *Federal Register* notice (63 FR 3142) and subsequently in the guidance the Agency 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") (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether a 510(k) is necessary for class II devices: (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 would still be subject to the limitations on exemptions.

III. Proposed Class II Device Exemption

FDA, on its own initiative, is proposing to exempt N95 filtering facepiece respirators (FFRs) and surgical N95 respirators (herein collectively referred to as N95s) from 510(k), subject to the conditions and limitations described in this section. FDA considers both of these devices to be a subset of "surgical apparel" intended to be worn by healthcare personnel to protect both the patient and the healthcare personnel from transfer of microorganisms, body fluids, and particulate material. As a result, these devices fall under the generic name "surgical apparel" and are classified in 21 CFR 878.4040(b)(1). In the *Federal Register* of June 24, 1988 (53 FR 23856), FDA issued a final rule classifying surgical apparel into class II (special controls). We are now announcing our intent to exempt a subset of surgical apparel devices currently regulated under product code MSH from 510(k) review. FDA has assessed the need for 510(k) against the criteria laid out in the Class II 510(k) Exemption Guidance and determined that these devices no longer require a 510(k) to provide reasonable assurance of safety and effectiveness. However, this exemption is limited and FDA's determination only applies to those N95s under the conditions listed below.

FDA has a Memorandum of Understanding (MOU) with the Centers for Disease Control and Prevention (CDC), acting through its National Institute for Occupational Safety and Health

(NIOSH) regarding oversight of N95s (Ref. 2). This agreement outlines the structure through which both Agencies will regulate N95s being proposed for exemption from 510(k). However, this MOU will not be effective unless and until, FDA publishes an order in the *Federal Register*, after reviewing comments, that sets forth its determination finalizing the 510(k) exemption.

Although FDA and CDC share a common public health mission, the Agencies have different statutory authorities and the distinct terminology could lead to confusion among stakeholders. In order to clearly identify the devices that are subject to this document , as well as the corresponding MOU, the following definitions are provided for the devices being proposed for exemption.

The N95 FFR is a single-use disposable, half-mask respiratory protective device that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is a class II device, regulated by FDA under 21 CFR 878.4040.

The surgical N95 respirator is a single-use, disposable respiratory protective device used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. The surgical N95 respirator is also a class II device, regulated by FDA under 21 CFR 878.4040.

As described in the MOU, the following conditions must be met for N95s to be 510(k) exempt: (1) application submitted to NIOSH is determined not to exceed the CDC and FDA mutually agreed upon threshold evaluation criteria and (2) such applicants must have met approval criteria and have NIOSH approval. N95s with applications that meet the mutually agreed upon threshold evaluation criteria and approval criteria and remain approved by NIOSH

would be exempt from FDA's 510(k) requirements under section 510(k) of the FD&C Act. Unless an N95 meets the mutually agreed upon threshold evaluation criteria and approval criteria and has NIOSH approval, the device would still be subject to 510(k) review; this includes devices with applications pending NIOSH review, as well as devices with no submitted applications.

N95s are the only devices included within the scope of the MOU. As such, this proposed exemption would only apply to devices currently regulated by FDA under product code MSH. If finalized, this exemption would not affect any other subset of surgical apparel classified under 21 CFR 878.4040. In addition to being subject to the general limitations to the exemptions found in 21 CFR 878.9 and the conditions of exemption identified in this document, these devices will also remain subject to current good manufacturing practices and other general controls under the statute. An exemption from the requirement of 510(k) 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.

IV. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA Guidance, "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff," February 19, 1998, available at

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.

2. "Memorandum of Understanding Between the Food and Drug Administration, Center for Devices and Radiological Health, and the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory," available at https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq., as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878 — GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. In § 878.4040, revise paragraph (b)(1) to read as follows:

§ 878.4040 Surgical apparel.

*****

(b) * * *

(1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering

surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

*****

Dated: November 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-25781 Filed: 11/29/2017 8:45 am; Publication Date: 11/30/2017]