Country	Listed person and address	**Federal Register** citation and date of publication
*	* * * *	* * *
	GenX Middle East FZE, a.k.a. GenX Systems LLC, #510–511 Le Solarium Building, Dubai Silicon Oasis, Dubai, UAE; *and* P.O. Box 121225, Office M07, Al Zahra, Khaleed Bin Al Waleed Road, Bur Dubai, Dubai, UAE.	83 FR ''[INSERT **FEDERAL REGISTER** PAGE NUMBER], May 17, 2018.''
	Roudah Al Hayat General Trading FZE, a.k.a. Rudha Al Hayat General Trading, a.k.a. Rouda Al Hayat General Trading, a.k.a. JSB Logistics, 406 Al Rhakaimi Building, Deira, Dubai, UAE; *and* #3204 Aspect Tower D, Sheikh Zayed Road, Dubai, UAE; *and* #1506 Aspect Tower D, Sheikh Zayed Road, Dubai, UAE *and* 901 Regal Tower, Business Bay, Dubai, UAE *and* 402 Al Fahad Building, Damascus Street, Dubai, UAE.	83 FR ''[INSERT **FEDERAL REGISTER** PAGE NUMBER], May 17, 2018.''
*	* * * *	* * *
	TEM International FZC, Dubai Silicon Oasis Headquarters Building, 4th Floor C&D Wings, P.O. Box 341041, Dubai, UAE.	83 FR ''[INSERT **FEDERAL REGISTER** PAGE NUMBER], May 17, 2018.''
*	* * * *	* * *

Dated: May 12, 2018.

Richard E. Ashooh,

Assistant Secretary for Export Administration.

[FR Doc. 2018–10528 Filed 5–16–18; 8:45 am]

BILLING CODE 3510–33–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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing this final order to exempt certain surgical apparel from premarket notification requirements, subject to conditions and limitations. FDA is limiting the 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. This exemption will decrease regulatory burden on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. All other class II devices classified under FDA's surgical apparel classification regulation continue to be subject to premarket notification requirements. FDA is also amending the codified language for the surgical apparel devices classification regulation to reflect this final determination.

DATES: This order is effective May 17, 2018.

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 Federal Food, Drug, and Cosmetic Act (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 shall 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. Device Description

FDA, upon its own initiative, is exempting 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 N95s 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 § 878.4040(b)(1) (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 exempting 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 exempt from 510(k). The MOU between NIOSH and FDA is now effective as part of this final order.

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 that are now exempt.

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 § 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 § 878.4040.

In the **Federal Register** of November 30, 2017 (82 FR 56763), FDA published a proposed order announcing its intent to exempt N95s from premarket notification [510(k)] requirements, subject to certain conditions and limitations, and provided opportunity for interested persons to submit comments by January 30, 2018. After reviewing the comments received (summarized in section IV), FDA is now providing its final determination for N95s by exempting this type of device from 510(k) requirements, subject to certain conditions and limitations as identified in this final order. FDA is also amending the codified language for the surgical apparel devices classification regulation to reflect this final determination. Persons with pending 510(k) submissions for devices that are now exempt from 510(k), subject to the conditions and limitations, should withdraw their submissions.

IV. Comments on the Proposed Exemption and FDA's Response

In response to the November 2017 proposed order announcing FDA's intent to exempt N95s from 510(k) requirements, FDA received submissions from four commenters—two from regulated industry, one from an industry association, and one from a consumer. Three commenters supported the implementation of the MOU with the CDC, acting through NIOSH, regarding oversight of N95s and exemption from 510(k) for this device type. FDA agrees with the three commenters that the exemption from 510(k) requirements will streamline the oversight of N95s without compromising the public health.

One commenter requested that these devices still be subject to 510(k) requirements to ensure safety of people using the disposable respiratory protective devices. Further, the commenter indicated that FDA's proposal should not be finalized because the sterility of these devices can greatly affect those working in the health field and patients being treated, and if these devices are not properly inspected or regulated, diseases could spread more easily from person to person. The commenter noted that because these devices will be used by surgical staff, it is even more important that the devices be inspected because surgery can involve open wounds or open body cavities, making it easier to spread disease or bodily fluids.

FDA notes in response to this commenter that N95s subject to this exemption from 510(k) are not provided sterile to the user. While FDA has exempted these devices from 510(k), the scientific evidence necessary to legally market N95s within this exemption has not changed. The majority of this testing has traditionally been reviewed by NIOSH. The conditions and limitations of exemption that FDA has identified in section V of this final order and § 878.4040(b)(1) will provide reasonable assurance of safety and effectiveness for N95s. 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. Accordingly, FDA did not modify the exemption or conditions and limitations of exemption proposed for N95s in response to this comment.

V. Conditions and Limitations of Exemption

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's and FDA's 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 are exempt from FDA's 510(k) requirements. Unless an N95 meets the mutually agreed upon threshold evaluation criteria and approval criteria and has NIOSH approval, the device is subject to 510(k) review; this includes devices with applications pending NIOSH review, as well as devices with no submitted applications. The threshold evaluation criteria are

codified into the conditions and limitations of exemption described in § 878.4040(b)(1).

N95s are the only devices included within the scope of the MOU. As such, this exemption only applies to devices currently regulated by FDA under product code MSH. This exemption does not affect any other subset of surgical apparel classified under § 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 final order, these devices will also remain subject to current good manufacturing practices and other general controls under the FD&C Act. 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.

This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulations. Specifically, regulated industry will no longer have to invest time and resources in 510(k)s, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review for devices in this exempted device type, subject to the conditions and limitations of the exemption.

VI. Paperwork Reduction Act of 1995

This order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart, E have been approved under OMB control number 0910–0120.

VII. 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, 21 CFR part 878 is 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, paragraph (b)(1) is revised to read as follows:

§ 878.4040 Surgical apparel.

* * * * *

(b) *Classification.* (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: May 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10563 Filed 5–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Parts 50 and 51

[Public Notice 10417]

RIN 1400–AD54

Passports

AGENCY: Department of State.

ACTION: Final rule; stay.

SUMMARY: The Department of State published a final rule in the **Federal Register** on May 11, 2018, amending the passport rules for the Department of State (the Department). The document stays the amendments in the May 11 rule until June 10, 2018.

DATES: Effective May 17, 2018, §§ 50.7(d), 50.11(b), 51.4(g)(1) and (8), 51.60(h) and (i), 51.62, 51.65, 51.66, and 51.70 through 51.74, are stayed until June 10, 2018.

FOR FURTHER INFORMATION CONTACT: Anita Mody, Office of Legal Affairs, Passport Services, (202) 485–6500, *PassportRules@state.gov.* Hearing- or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department of State published a final rule on May 11, 2018 (83 FR 21872), which provided that the rule was effective on the date of publication. This document provides a stay of the amendments in that rule until 30 days after the date of the May 11, 2018, publication. The Regulatory Analysis published with that final rule is unchanged by this publication.

List of Subjects

22 CFR Part 50

Citizenship and naturalization.

22 CFR Part 51

Administrative practice and procedure, Drug traffic control,