November 14, 2022

Foshan Nanhai Plus Medical Co., Ltd.
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
14F, Building C, Ancillary Project of Phase IV
Standard Industrial Park Guangzhou International Bio-Island
Guangzhou, Guangdong 510320
China

Re: K222480
Trade/Device Name: Standard Surgical Gown (AAMI Level 2); Reinforced Surgical Gown (AAMI Level 2)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: August 17, 2022
Received: August 17, 2022

Dear Olivia Meng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222480

Device Name

Standard Surgical Gown (AAMI Level 2); Reinforced Surgical Gown (AAMI Level 2)

Indications for Use *(Describe)*

The Standard Surgical Gown (AAMI Level 2) and Reinforced Surgical Gown (AAMI Level 2) are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate material.

The Standard Surgical Gown (AAMI Level 2) and Reinforced Surgical Gown (AAMI Level 2) meets the level 2 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

The Standard Surgical Gown (AAMI Level 2) and Reinforced Surgical Gown (AAMI Level 2) have been validated using an ethylene oxide sterilization process. The Standard Surgical Gown (AAMI Level 2) and Reinforced Surgical Gown (AAMI Level 2) are also sold as bulk single-use, non-sterile, to repackager/relabeler establishments for further packaging and sterilization using the validated EtO sterilization method according to ISO 11135-1 prior to being provided to the end user.

Models without Hand Towels and Wrap:

Standard Surgical Gown (AAMI Level 2)			Reinforced Surgical Gown (AAMI Level 2)		
☐ PM3501SGN	M	Non-sterile	☐ PM3501RGN	M	Non-sterile
☐ PM3502SGN	L	Non-sterile	☐ PM3502RGN	L	Non-sterile
☐ PM3503SGN	XL	Non-sterile	☐ PM3503RGN	XL	Non-sterile
☐ PM3504SGN	2XL	Non-sterile	☐ PM3504RGN	2XL	Non-sterile
☐ PM3505SGN	3XL	Non-sterile	☐ PM3505RGN	3XL	Non-sterile
☐ PM3501SGS	M	Sterile	☐ PM3501RGS	M	Sterile
☐ PM3502SGS	L	Sterile	☐ PM3502RGS	L	Sterile
☐ PM3503SGS	XL	Sterile	☐ PM3503RGS	XL	Sterile
☐ PM3504SGS	2XL	Sterile	☐ PM3504RGS	2XL	Sterile
☐ PM3505SGS	3XL	Sterile	☐ PM3505RGS	3XL	Sterile

Models with Hand Towels and Wrap:

Standard Surgical Gown (AAMI Level 2)			Reinforced Surgical Gown (AAMI Level 2)		
☐ PM3511SGN	M	Non-sterile	☐ PM3511RGN	M	Non-sterile
☐ PM3512SGN	L	Non-sterile	☐ PM3512RGN	L	Non-sterile
☐ PM3513SGN	XL	Non-sterile	☐ PM3513RGN	XL	Non-sterile
☐ PM3514SGN	2XL	Non-sterile	☐ PM3514RGN	2XL	Non-sterile
☐ PM3515SGN	3XL	Non-sterile	☐ PM3515RGN	3XL	Non-sterile
☐ PM3511SGS	M	Sterile	☐ PM3511RGS	M	Sterile
☐ PM3512SGS	L	Sterile	☐ PM3512RGS	L	Sterile
☐ PM3513SGS	XL	Sterile	☐ PM3513RGS	XL	Sterile
☐ PM3514SGS	2XL	Sterile	☐ PM3514RGS	2XL	Sterile
☐ PM3515SGS	3XL	Sterile	☐ PM3515RGS	3XL	Sterile

Type of Use *(Select one or both, as applicable)*

[ ] Prescription Use (Part 21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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