February 10, 2021

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K202605
Trade/Device Name: Standard Procedure Mask, Standard Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 20, 2020
Received: November 19, 2020

Dear Diana Hong:

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,

For CAPT Elizabeth Claverie, M.S.
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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202605

Device Name

Standard Procedure Mask; Standard Surgical Mask

Indications for Use *(Describe)*

The device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K202605

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 01/29/2021

2. Sponsor Identification

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Devices

Trade Name: Standard Procedure Mask; Standard Surgical Mask
Common Name: Surgical Face Mask

Regulatory Information
Classification Name: mask, surgical
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital;

Indication for use:
The device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Device Description:
The proposed devices, Standard Procedure Mask and Standard Surgical Mask, are a three-layer, single-use, flat-pleated mask. Both the two masks have the same indications for use. The Standard Procedure Mask is an ear-loop surgical mask, and the Standard Surgical Mask is a tie-on surgical mask. The color of the proposed devices is blue. They are provided in non-sterile.

5. Identification of Predicate Device

510(k) Number: K153496
Product Name: Disposable Surgical Face Mask

6. Summary of Non-Clinical Testing

The following performance data has been provided to demonstrate that the subject device meet the acceptance criteria in the standard.

Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
Resistance to Penetration by Synthetic blood ASTM F1862/F1862M-17 Standard Test Method for	The test was performed in accordance with ASTM F1862-17 Standard Test Method for Resistance of	No penetration at 120 mmHg	Pass at 120mmHg

Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test sample from possible exposure to blood and other body fluids		
Bacterial Filtration Efficiency ASTM F2101-2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	The test was performed in accordance with ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, using a Biological Aerosol of Staphylococcus aureus to determine the bacterial filtration efficiency (BFE) of the test article.	⩾98%	Average 98.61%
Particulate Filtration Efficiency ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres	The test was performed in accordance with ASTM F2299-03 (Reapproved 2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres, to determine the Particle Filtration Efficiency.	⩾98%	Average 98.58%
Differential Pressure EN 14683:2019 Medical face masks- Requirements and test methods	The test was performed in accordance with EN 14683:2019 Medical face masks-Requirements and test methods, to determine the differential pressure.	<6.0 mm H_2O/cm^2	Average 4.41 mm H_2O/cm^2
Flammability 16 CFR 1610 Standard for	The test was performed in accordance with 16 CFR	Class I	Class I

the Flammability of Clothing Textiles Corrections	1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES to evaluate the flammability of the test sample.		

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Surgical Mask

ITEM	Proposed Devices K202605	Predicate Device K153496	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Mask style	Flat pleated	Flat pleated	Same
Mask color	Blue	Blue	Same
Design Feature	Ear-loop or tie-on	Ear-loop or tie-on	Same
Dimension (mm)	175×95	175×95	Same
Level	Level 2	Level 2	Same
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate efficiency level	≥98%	≥98%	Same
Bacterial filtration level	≥98%	≥98%	Same
Differential pressure	＜6.0 mm H_2O/cm^2	4.2 mmH_20/cm^2	Different 1

Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Single use	Single use	Single use	Same
Ear strap	Polyester and spandex and Spunbonded nonwoven	Polyester and Spun-bond polypropylene	Different 2
Nose clip	Plastic	Malleable aluminum wire	Different 2
Mask body	Spunbonded nonwoven and Melt-blown nonwoven fabric	Spun-bond polypropylene and Melt blown polypropylene filter	Different 2
Cytotoxicity	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non‐cytotoxic.	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non‐cytotoxic.	Same
Sensitization	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Same
Irritation	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Same
Sterility	Non-sterile	Non-sterile	Same

Different 1- Differential pressure

The test result for different pressure for the proposed device is different from predicate devices. The differential pressure test standard has been updated to EN14683:2019, Annex C in ASTM F2100:2019. The differential pressure test of the proposed device was conducted according to EN14683:2019, Annex C, and the test result demonstrate that the differential pressure of the proposed device meet the requirements of level 2 specified in ASTM F2100:2019. Thus, this difference does not affect substantially equivalence between the proposed device and predicate devices.

Different 2- Patient Contacting Material

The patient contact material for the propose device is different from predicate devices. However, biocompatibility tests have been conducted on the propose device and the test result does not show any adverse effect. Therefore, this difference does not affect substantially equivalence between the proposed device and predicate devices.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K153496.