March 3, 2022

3A Medical Products Co., Ltd
Mary Mejaes
Consultant
Yu An Industrial Park 230001
Liu An, Anhui
China

Re: K202598
Trade/Device Name: 3 Layer Surgical Mask with Ear Loops Level 1, 3 Layer Surgical Mask with Ties Level 1, 3 Layer Surgical Mask with Ear Loops Level 2, 3 Layer Surgical Mask with Ties Level 2, 3 Layer Surgical Mask with Ear Loops Level 3, 3 Layer Surgical Marks with Ties Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX

Dear Mary Mejaes:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 6, 2021. Specifically, FDA is updating this SE Letter for a missing trade name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Clarence W. Murray III, PhD., OHT4: Office of Surgical and Infection Control Devices, 301-796-0270, clarence.murray@fda.hhs.gov.

Sincerely,

Liqun Zhao -S

For Clarence W. Murray III, PhD.
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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

May 6, 2021

3A Medical Products Co., Ltd
Mary Mejaes
Consultant
Yu An Industrial Park 230001
Liu An, Anhui
China

Re: K202598
Trade/Device Name: 3 Layer Surgical Mask with Ear Loops Level 1, 3 Layer Surgical Mask with Ties Level 1, 3 Layer Surgical Mask with Ear Loops Level 2, 3 Layer Surgical Mask with Ties Level 2, 3 Layer Surgical Mask with Ear Loops Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 20, 2021
Received: March 1, 2021

Dear Mary Mejaes:

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,

Ryan Ortega -S

Ryan Ortega, PhD
Acting 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)*
k202598

Device Name

3 Layer Surgical Mask with Ear Loops, Level 1
3 Layer Surgical Mask with Ear Loops, Level 2
3 Layer Surgical Mask with Ear Loops, Level 3
3 Layer Surgical Mask with Ties, Level 1
3 Layer Surgical Mask with Ties, Level 2
3 Layer Surgical Mask with Ties, Level 3

Indications for Use *(Describe)*

This mask is intended to be worn to protect both the patient and healthcare worker from the transfer of microorganisms, body fluids and particulate material. This mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use 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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date of Summary Preparation: April 29, 2021
Type of 510K: Traditional
510K Number: K202598

1. **Applicant:** 3A Medical Products Co., Ltd.
   Address: Yu An Industrial Park, 230001
   Liu An, Anhui Province
   People's Republic of China
   Tel No. 86-564-3611700
   Fax No. 86-5643611700
   Email Address: info@3a-medical.cn
   Consultant: Mary Mejaes

2. **Proprietary Device Name**
   3 Layer Surgical Mask with Ear Loops: Level 1
   3 Layer Surgical Mask with Ties: Level 1
   3 Layer Surgical Masks with Ear Loops: Level 2
   3 Layer Surgical Masks with Ties: Level 2
   3 Layer Surgical Masks with Ear Loops: Level 3
   3 Layer Surgical Masks with Ties: Level 3

3. **Regulatory Information:**
   Classification Name: Surgical Face Masks/Apparel
   Classification: Class II
   Product Code: FXX
   Regulation No. 21 CFR 878.4040

4. **Predicate Device:**
   510K Number: K160269
   Manufacturer: SAN-M Package Co., Ltd.
   Device Name: Surgical Face Masks (Ear Loops and Tie On)

5. Indications for Use/Intended Use:

This mask is intended to be worn to protect both the patient and healthcare worker from transfer of microorganisms, body fluid and particulate material. This mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use device and is provided non-sterile.

6. Device Description:

These 3 Layer Surgical Masks: Level 1, Level 2 or Level 3 (with Ear Loops or Ties) are 3 layer, flat-folded masks constructed of 100% nonwoven polypropylene materials. The masks are provided with Ear Loops (Polyester/Spandex) or Ties (Polypropylene). A malleable nose strip is placed within the binding for comfort and individualized fit. These masks meet the acceptance criteria for ASTM F 2100, Level 1, Level 2 or Level 3 performance standards and are provided in blue. These masks are single use and provided non-sterile.

3 Layer Surgical Masks Model Numbers

Table A, Model Nos.

Barrier Levels	**Ear Loops**	**Ties**
Level 1	Ref: 1000E	Ref: 1000T
Level 2	Ref: 2000E	Ref: 2000T
Level 3	Ref: 3000E	Ref: 3000T

7. Comparison of Technological Characteristics

Table B, Comparison of Characteristics

Feature	**Proposed Device Surgical Masks with Ear Loops or Ties, Level 1, Level 2, Level 3**	**Predicate Device Surgical Face Masks Ear Loops and Tie-on Level 1, Level 2 and Level 3**	**Comparison of Characteristics Remarks**
510 (k) No	K202598	K160269	-
Manufacturer	3A Medical Products Co., Ltd	San-M Package Co. Ltd	-
Common Name	Surgical Mask	Surgical Mask	Identical
Classification	Class II	Class II	Identical
Product Code	FXX	FXX	Identical

Indications for Use	This mask is intended to be worn to protect both the patient and healthcare worker from the transfer of microorganisms, body fluids and particulate material.This mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use device provided non-sterile.	The 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 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.	Same

Outer Layer	Polypropylene	Polypropylene	Similar Please see Note 1
Inner Layer	Polypropylene	Polypropylene	Similar Please see Note 1
Filter Media	1. Polypropylene Spunbond 2.Polypropylene Meltblown	1. Polypropylene Spunbond 2.Polypropylene Meltblown	Similar Please see Note 1
Nose Strip	Polyethylene coated Steel Wire	Polyethylene coated Steel Wire	Same
Ear Loop/Ties	Ear Loops: Polyester/Spandex Ties: Polypropylene Spunbond	Ear Loop: Polyester, Polyurethane Ties Polypropylene Spunbond or Polyester Spunbond	Similar
Color	Blue	White or Blue	Similar
Dimensions	9.5±1cm x 17.5 cm ±1 cm	95 ±3mm x 175±5mm, 90±3mm x 180mm	Similar
Mask Style	Flat Pleated	Flat Pleated	Same
Sterility	Non-Sterile	Non-Sterile	Same

Note 1: The outer layer, inner layer and filter media of the proposed devices have the same material content but with different weights in order to meet the safety and effectiveness of each barrier level. They still meet the requirements of essential performance standard ISO 10993.

The proposed device under this premarket notification submission 510(k) K202598 is the same or similar in design, indications for use, technological characteristic and is composed of the same or similar components as the predicate device 510(k) K160269.

8. Summary of Non-Clinical Testing

Table C, Test Methods Used

	Proposed Device Surgical Masks with Ear Loops or Ties Level 1, Level 2, Level 3	**Predicate Device Surgical Face Masks Ear Loops and Tie-on Level 1, Level 2 ,Level 3**
Fluid Resistance	ASTM F 1862F/1862M-2017	ASTM F1862
Particulate Filtration Efficiency	ASTM F 2299/F2299M-2003(2017)	ASTM F2299
Bacteria Filtration Efficiency	ASTM F2101:2019	ASTM F2101
Differential Pressure	EN14683:2019 +AC2019 (E) Annex C	MIL-M36945C
Flammability	16 CFR 1610: 2019	16 CFR 1610
Biocompatibility	ISO10993-5:2009 ISO 10993-10:201	ISO 10993

Table D, Performance Testing

Test Methods	**Proposed Device Surgical Masks (Ear Loops or Ties)**			**Predicate Device Level 1**	**Predicate Device Level 2**	**Predicate Device Level 3**	**Comparison**
ASTM F2100	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Same
ASTM F1862	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Same
ASTM 2299	Pass at 98.86%	Pass at 98.8%	Pass at 98.6%	Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Similar
ASTM F2101	Pass at 99.9%	Pass at 99.9%	Pass at 99.9%	Pass at >98%	Pass at >98%	Pass at >99%	Similar
EN14683 for proposed and Mil-M26945C for the predicate	Pass at 4.1 mm H_2O/cm^2	Pass at 4.0 mm H_2O/cm^2	Pass at 4.53 mm H_2O/cm^2	Pass at 2.0mm H_2Ocm^2	Pass at 1.6mm H_2O/cm^2	Pass at 2.5mm H_2O/cm^2	Similar

Table E, Flammability and Biocompatibility Testing Results

	Proposed Device Levels 1, 2 and 3			**Predicate Device Level 1, 2 and 3**	**Comparison**
16 CFR 1610	Class 1	.Class 1	Class 1	Class 1	Same
Cytotoxicity ISO 10993-5:2010	Under the conditions of this study the test article have no potential toxicity to L929 cells	Under the conditions of this study the test article have no potential toxicity to L929 cells	Under the conditions of this study the test article have no potential toxicity to L929 cells	Under the conditions of the study the subject device was non-cytotoxic.	Similar
Irritation ISO10993-10:2010	Under the experimental conditions the test article has no potential skin irritation on rabbits in the extraction method.	Under the experimental conditions the test article has no potential skin irritation on rabbits in the extraction method.	Under the experimental conditions the test article has no potential skin irritation on rabbits in the extraction method.	Under the conditions of the study the subject device was non-irritating.	Similar
Sensitization ISO 10993-10:2010	Under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method	Under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction Method	Under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method	Under the conditions of the study the subject device was non-sensitizing.	Similar

The proposed models under this premarket notification submission have similar performance characteristics and conform to the same Recognized Consensus Standards. These standards include testing that covers Bacterial Filtration Efficiency, Particulate Filtration Efficiency, Fluid Resistance, Flammability, Differential Pressure (Breathability) and Biocompatibility. Differences between the Proposed 3 Layer Surgical Masks (Ear Loop and Tie on) and the predicate devices did not raise any new concerns regarding safety and effectiveness. Both meet the Recognized Consensus Standards acceptance criteria.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject device in 510(k) submission K202598, 3 Layer Surgical Masks with Ear Loops or Ties, Level 1, Level 2, and Level 3 is as safe and effective and performs as well or better than the legally marketed predicate device cleared under 510(k) K160269.