March 13, 2023

Wuhan Huashida Protective Products Co., Ltd.
Mei Chen
Manager
No. 511 Weihu Rd, Shamao St, Hannan District
Wuhan, Hubei 430090
China

Re: K221352
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 27, 2023
Received: February 27, 2023

Dear Mei Chen:

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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K221352

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
The Surgical Face Mask 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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510(k) summary

I Submitter

Device submitter: Wuhan Huashida Protective Products Co., Ltd.
No.511 Weihu Rd, Shamao St, Hannan district, Wuhan, Hubei, China

Contact person: Chen Mei
Manager
Phone: +86-18971272798
E-mail: Happy@huashida168.cn

II Proposed Device

Trade/Device Name:	Surgical Face Mask
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Regulatory Class:	Class II
Product code:	FXX
Review Panel:	General Hospital

III Predicate Devices

510(k) Number:	K202903
Trade/Device Name:	Surgical Face Mask
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Classification:	Class II
Product Code:	FXX
Manufacturer	Rizhao Sanqi Medical & Health Articles Co., Ltd

IV Indication for use

The Surgical Face Mask 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.

V Device Description

The Surgical Face Mask is 3-layer, and it is two model is HSD-TYP2R (Ear loops) and HSD-TYP2RT (Tie-On). Flat-folded masks constructed of nonwoven polypropylene materials.

The mask is provided with ear loops (spandex and polyester) or tie tapes (spun-bond polypropylene). A malleable nose clip is placed in the layers of facemask for comfort and individualized fit. The surgical face mask color is blue. Product is Level 3 based on ASTM F2100-19. The surgical face mask is single-use, disposable devices, provided non-sterile.

VI Summary of Technological characteristics

<table>
<tr><th>Item</th><th>Subject device</th><th>Predicate device (K202903)</th><th>Discussion</th></tr>
<tr><td>Product name</td><td>Surgical Face Mask</td><td>Surgical Face Mask</td><td>NA</td></tr>
<tr><td>Product model</td><td>HSD-TYP2R, HSD-TYP2RT</td><td>Level 3 Surgical Face Mask models: SQ-3001, SQ-3001H</td><td>NA</td></tr>
<tr><td>Classification</td><td>Class II Device, FXX (21 CFR878.4040)</td><td>Class II Device, FXX (21 CFR878.4040)</td><td>Identical</td></tr>
<tr><td>Intended use</td><td>The Surgical Face Mask 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.</td><td>The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. When worn properly, 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. This is a single use, disposable device(s), provided non-sterile</td><td>Identical</td></tr>
<tr><td>Component and Materials</td><td><table><tr><th>Structure</th><th>Materials</th></tr><tr><td>Outer layer</td><td rowspan="2">Spun-bond polypropylene</td></tr><tr><td>Inner layer</td></tr><tr><td>Filter layer</td><td>melt-blown polypropylene</td></tr><tr><td>Nose clip</td><td>malleable aluminum wire</td></tr><tr><td>Ear loops</td><td>spandex and polyester</td></tr><tr><td>Tie Tapes</td><td>spun-bond polypropylene</td></tr></table></td><td><table><tr><th>Structure</th><th>Materials</th></tr><tr><td>Outer layer</td><td>Polypropylene</td></tr><tr><td>Inner layer</td><td>Polypropylene</td></tr><tr><td>Filter layer</td><td>3 Flat leated: Melt-blown Polypropylene</td></tr><tr><td>Nose clip</td><td>Steel coated by polypropylene</td></tr><tr><td>Ear loops</td><td>Spandex</td></tr><tr><td>Tie Tapes</td><td>Spunbond Polypropylene</td></tr></table></td><td>Different</td></tr>
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Section 3-510(k) Summary

Item	Subject device	Predicate device (K202903)	Discussion
Mask style	Flat-pleated	Flat-pleated	Identical
Design Features	Ear Loops, Tie-on	Ear Loops, Tie-on	Identical
Mask style	3 Flat Pleated	3 Flat Pleated / 4 Flat Pleated	Similar
Color	Blue	Blue, white, pink, green, yellow	Similar
Dimension (Length)	175±10mm	175±5mm	Similar
Dimension (Width)	90±10mm	95±5mm	Similar
ASTM F2100 Level	Level 3	Level 3	Identical
OTC use	Yes	Yes	Identical
Sterility	Non-Sterile	Non-Sterile	Identical
Use	Single Use, Disposable	Single Use, Disposable	Identical
Particulate filtration efficiency	Meet ASTM F2299-17	Meet ASTM F2299-17	Identical
Bacterial filtration efficiency	Meet ASTM F2101-19	Meet ASTM F2101-19	Identical
Differential pressure	Meet EN 14683: 2019, Annex C	Meet EN 14683: 2019, Annex C	Identical
Flammability	Meet 16 CFR 1610	Meet 16 CFR 1610	Identical
Fluid resistance	Meet ASTM F1862-17	Meet ASTM F1862-17	Identical
Biocompatibility	Non-cytotoxic, Non-sensitizing, non-irritating	Non-cytotoxic, Non-sensitizing, non-irritating	Identical

Different - Patient Contacting Material

The patient contacting material for the proposed device is different from the predicate devices. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

VII Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the

Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F2100 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683 Medical face masks- Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization

For Surgical Face Mask Performance

Items	Purpose	Acceptance Criteria	Result
Fluid Resistance Performance	The purpose of the performance testing is to demonstrate The functionality of the subject device	29 out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency		⩾ 98%	Pass
Bacterial Filtration Efficiency		⩾ 98%	Pass
Differential Pressure		<6.0 mmH_2O/cm^2	Pass
Flammability		Class 1	Pass

For Surgical Face Mask Biocompatibility

Items	Purpose	Acceptance Criteria	Result
Cytotoxicity	The purpose of the testing is to demonstrate safety of the subject device	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing.

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX 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 K202903.