April 2, 2021

Guangdong Winsun Personal Care Products Co.,Ltd
% Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K210023
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 28, 2020
Received: January 4, 2021

Dear Grace Liu:

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 Ryan Ortega Ph. D
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)*
K210023

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
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(s), 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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

1. Contact Details

1.1 Applicant information

Applicant Name	Guangdong Winsun Personal Care Products Co.,Ltd
Address	No.1 Guangxing Road, Xiqiao Sci-Tec Industrial Park, Xiqiao Town, Nanhai District, Foshan City, Guangdong Province, P.R.China
Contact person	Dong Pingping
Phone No.	+86-139 2990 4428
E-mail	dongpingping@gdwinsun.cn
Date Prepared	2020-12-12

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86-755-86069197
Contact person	Grace Liu; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Surgical Face Mask
Common name	Surgical Face Mask
Model	YS0002
Classification name	Mask, Surgical
Review Panel	General Hospital
Product code	FXX
Device Class	Ⅱ
Regulation No.	21 CFR 878.4040

3. Legally Marketed Predicate Device

Trade Name	Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G

	Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G
510(k) Number	K133070
Product Code	FXX
Manufacturer	BH Medical Products Co., Ltd.

4. Device Description

The proposed devices are three-layer, flat pleated masks. A Surgical Face Mask is composed of a mask body, a nose piece and two ear loops. The mask body is manufactured with three layers, the inner layer and the outer layer are made of spunbond polypropylene nonwoven fabric, and the middle layer is made of meltblown polypropylene nonwoven fabric.

The model of proposed device, ear-loop, is held in place over the user's mouth and nose by two elastic ear loops welded to the mask body. The elastic ear loops are knitted elastic loops (made of polyester and spandex).

The nose piece is in the layers of face mask to allow the user to fit the face mask around their nose, which is a steel wire with polyethylene covering.

The proposed devices are provided non-sterile and are intended to be single use, disposable devices.

5. Intended Use/Indication for Use

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(s), provided non-sterile.

6. Substantial Equivalence Comparison

Comparison item	Proposed Device	Predicate Device (K133070)	Comment
Manufacturer	Guangdong Winsun Personal Care Products Co., Ltd	BH Medical Products Co., Ltd.	None
Product name	Surgical Face Mask	Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G	None
Product Code	FXX	FXX	Same

Regulation Number		21 CFR § 878.4040			21 CFR § 878.4040			Same
Classification		Class II			Class II			Same
OTC use		Yes			Yes			Same
Indications for Use		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(s), 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 facemasks 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
Design feature		Ear-loop			Ear-loop/Tie-on			Similar
Mask style		3 flat pleated			3 flat pleated			Same
Single use		Yes			Yes			Same
Color		Blue			Blue, Green			Similar
Specifications and dimensions		(17.5±1)cm×(9.5±0.5)cm (6.9”±0.39”)×(3.7”±0.20”)			(6.8”±0.25”)×(3.5”±0.25”) (6.8”±0.25”)×(4.2”±0.25”)			Similar
Sterility		Non-sterile			Non-sterile			Same
Materials	Outer layer	Spunbond Polypropylene			Spunbond Polypropylene			Same
	Middle layer	Meltblown Polypropylene			Meltblown Polypropylene			Same
	Inner layer	Spunbond Polypropylene			Spunbond Polypropylene			Same
	Nose piece	Steel wire with polyethylene covering			Aluminum wire			Different (Issue 1)
	Ear loop	Polyester and spandex			Polyester			Different (Issue 2)
ASTM F2100 Level		Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Same
Fluid Resistance		Meet ASTM F1862			Meet ASTM F1862-07			Same
Particulate		Meet ASTM F2299			Meet ASTM F2299-03			Same

Filtration Efficiency			
Bacterial Filtration Efficiency	Meet ASTM F2101	Meet ASTM F2101-07	Same
Differential Pressure (Delta P)	Meet EN 14683	Meet MIL-M-36954C	Different (Issue 3)
Flammability (16CFR 1610)	Class 1	Class 1	Same
Biocompatibility	Non-cytotoxic, non-sensitizing, non-irritating	Non-cytotoxic, Non-sensitizer, non-irritant	Same

Issue 1 and Issue 2: The differences in the materials do not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials.

Issue 3: The Differential Pressure test of the proposed device was conducted in accordance with the method specified in EN 14683:2019, Annex C that is the test method specified in ASTM F2100-19. ASTM F2100-19 is the recognized consensus standard [Rec# 6-425] which is the standard specification for performance of materials used in medical face masks. And the Differential Pressure performance of the proposed device meets the requirement of ASTM F2100-19.

7. Non-clinical Testing

7.1 Physical performance testing

The performances of Surgical Face Mask conform to ASTM F 2100-19 and the following performance tests have been conducted to demonstrate the effectiveness of device.

- Bacterial filtration efficiency (BFE): pass (ASTM F2101)
- Particulate filtration efficiency (PFE): pass (ASTM F2299)
- Differential pressure (Delta-P): pass (EN 14683)
- Fluid Resistance: pass (ASTM F1862)
- Flammability: Class 1 (16 CFR Part 1610)

7.2 Biocompatibility testing

Surgical Face Mask has been subjected to biocompatibility studies to demonstrate the safety according to ISO 10993-1, “Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process”. The following tests have been conducted.

- In Vitro Cytotoxicity (ISO 10993-5): non-cytotoxic;
- Skin Irritation (ISO 10993-10): non-irritating;

- Skin Sensitization (ISO 10993-10): non-sensitizing.

There is no additional safety risk for the proposed device when compared with the predicate device.

8. Clinical testing

Clinical testing was not performed for the proposed device.

9. Conclusion

Indications for Use, material, design feature, specifications and technological characteristics for the proposed device are similar to the predicate device (K133070). The non-clinical performance testing demonstrates that the proposed device is substantially equivalent to the legally marketed predicate device (K133070). Therefore, the results show that it is Substantially Equivalent (SE) between the proposed device and the predicate device.