April 11, 2021

Guangdong GoodFeeling Hygiene Material Tec 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: K202761
Trade/Device Name: Medical Surgical Mask (Non-sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 15, 2020
Received: September 21, 2020

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,

Ryan Ortega -S

Ryan Ortega, PhD
Acting Assistant Director
THT4B2: Personal Protective Equipment, Reprocessing & Disinfection Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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)*
K202761

Device Name
Medical Surgical Mask (Non-sterile)

Indications for Use *(Describe)*
The medical surgical 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.

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510(k) Summary

K202761

1. Contact Details

1.1 Applicant information

Applicant Name	Guangdong GoodFeeling Hygiene Material Tec Co., Ltd.
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Date Prepared	Apr. 2, 2021

1.2 Submission Correspondent

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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	Medical Surgical Mask (Non-sterile)
Common name	Medical Surgical Mask
Model	GFYY95
Classification	II
Classification name	Mask, Surgical
Product code	FXX
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 device is a three-layer, flat pleated mask. Each 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 the 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 made of knitted elastic loops (made of nylon and spandex).

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

The proposed device is provided non-sterile and is intended to be a single use, disposable device.

5. Intended Use/Indication for Use

The medical surgical 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

Table 1 Substantial Equivalence Comparison

Item	Proposed Device (K202761)	Predicate Device (K133070)	Comment
Product name	Medical Surgical Mask (Non-sterile)	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
Manufacturer	Guangdong GoodFeeling Hygiene Material Tec Co., Ltd.	BH Medical Products Co., Ltd.	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 medical surgical 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	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 face masks are intended for use in infection control practices to reduce the potential exposure to	Same

		blood and body fluids. This is a single use, disposable device(s), provided non-sterile.			blood and body fluids. This is a single use, disposable device(s), provided non-sterile.			
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		Length: 18cm±1cm (7.1''±0.39") Width: 9.5cm(3.7")±1cm (3.7"±0.39")			Length: 6.8" ±0.25" Width:3.5"+/-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	Galvanized wire with polyethylene covering			Aluminum wire			Different (Issue 1)
	Ear loop	Nylon and spandex			Polyester			Different (Issue 2)
ASTM Level (ASTM F2100-19)		Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Same
Fluid Resistance		Pass at 80 mmHg, 120 mmHg and 160 mmHg (ASTM F1862)			Meet ASTM F1862-07			Similar
Bacterial Filtration Efficiency		Pass at 99.56%~99.99% (ASTM F2101)			Meet ASTM F2101-07			Similar
Particulate Filtration Efficiency		Pass at 98.07%~99.24% (ASTM F2299)			Meet ASTM F2299-03			Similar
Differential Pressure (Delta-P)		Pass at (3.4~3.9) mmH_2O/cm^2 (EN 14683)			Meet MIL-M-36954C			Different (Issue 3)
Flammability		Pass at Class 1 (16 CFR 1610)			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

Non-clinical testing was conducted to verify that the proposed device met all design specifications as

similar to the predicate device. The tests were conducted according to the following standards, and the results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a riskmanagement process
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for in Vitro cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- 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
- EN 14683:2019+AC:2019 Medical Face Masks - Requirements and Test Methods
- ASTM F2299/F2299M-03(R2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- 16 CFR 1610 Standard for the Flammability of Clothing Textiles

Table 2 Performance Testing

Test	**Purpose**	**Acceptance Criteria**	**Results (Statistics of three lots)**	**Verdict**
Fluid Resistance (ASTM F1862)	Verify the fluid resistance of the proposed device can simultaneously meet the requirements for Level 1, Level 2 and Level 3 specified in ASTM F2100-19.	Level 1: 29 out of 32 pass at 80 mmHg	32 out of 32 pass at 80 mmHg	Pass
		Level 2: 29 out of 32 pass at 120 mmHg	32 out of 32 pass at 120 mmHg	Pass
		Level 3: 29 out of 32 pass at 160 mmHg	32 out of 32 pass at 160 mmHg	Pass
Bacterial filtration efficiency (BFE) (ASTM F2101)	Verify that bacterial filtration efficiency of the proposed device can simultaneously meet the requirements for Level 1, Level 2 and Level 3 specified in ASTM F2100-19.	Level 1: ≥95%	99.56%~99.99%	Pass
		Level 2: ≥98%		Pass
		Level 3: ≥98%		Pass
Particulate filtration efficiency (PFE) (ASTM F2299)	Verify that particulate filtration efficiency of the proposed device can simultaneously meet the requirements for Level 1, Level 2 and Level 3 specified in ASTM F2100-19.	Level 1: ≥95%	98.07%~99.24%	Pass
		Level 2: ≥98%		Pass
		Level 3: ≥98%		Pass
Differential pressure (Delta-	Verify that differential pressure of the proposed device can	Level 1: < 5.0 mmH_2O/cm^2	(3.4~3.9) mmH_2O/cm^2	Pass

P) (EN 14683)	simultaneously meet the requirements for Level 1, Level 2 and Level 3 specified in ASTM F2100-19.	Level 2: < 6.0 mmH_2O/cm^2		Pass
		Level 3: < 6.0 mmH_2O/cm^2		Pass
Flammability (16 CFR 1610)	Verify that Flammability of the proposed device can simultaneously meet the requirements for Level 1, Level 2 and Level 3 specified in ASTM F2100-19.	Level 1: Class 1	Class 1	Pass
		Level 2: Class 1		Pass
		Level 3: Class 1		Pass

Table 3 Biocompatibility Testing

Test	Purpose	Acceptance Criteria	Result
In vitro Cytotoxicity (ISO 10993-5)	Verify that the proposed device extract is non-cytotoxic.	The extract is non-cytotoxic under the research conditions.	Pass
Skin Irritation (ISO 10993-10)	Verify that the proposed device extract is non-irritating.	The polar and non-polar extracts are non-irritating under the research conditions.	Pass
Skin Sensitization (ISO 10993-10)	Verify that the proposed device extract is non-sensitizing.	The polar and non-polar extracts are non-sensitizing under the research conditions.	Pass

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusions

Indications for Use, materials, 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 as safe and effective as the legally marketed predicate device (K133070). Therefore, the results show that it is Substantially Equivalent (SE) between the proposed device and the predicate device.