April 11, 2021

Customfab, INC.
% Laura Nygard
RAQA Consultant, Lean RAQA
Lean RAQA, LLCX
12602 N Summer Wind Drive
Marana, Arizona 85658

Re: K203012
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 8, 2021
Received: March 9, 2021

Dear Laura Nygard:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203012

Device Name
Surgical Mask

Indications for Use *(Describe)*
The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material in infection control practices to reduce the potential exposure of the wearer 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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1. Applicant Information

Company Name	CUSTOM FAB, INC.
Establishment Registration Number	2031000
Phone Number	(714) 891-9119
Company Street Address	7345 Orangewood Ave
Fax Number	714-891-1699
City	GARDEN GROVE
State	CA
Country	US
Zip Code	92841

2. Contact Person

Full Name	Erentia Gillmer
Job Title	Brand Director
Phone	(714) 891-9119 X 231
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3. Correspondent Information

Full Name	Laura Nygard
Job Title	RAQA Consultant, Lean RAQA
Phone	(734) 807-1282
Email	lauran@leanraqa.com

4. Date of Preparation

Date of Preparation	04/05/2021

5. Device Information

Table 1 – Device Information

Trade Name	Surgical Mask
Common or Usual Name	Surgical Apparel
Classification Name	21 CFR 878.4040
Regulatory Class	2
Product Code	FXX

6. Predicate Devices

Table 2 – Predicate Device(s)

Predicate Type	510(k) Number	Name of Device	Name of Manufacturer
Primary Device	K201729	Medical Mask	Zhende Medical Co., Ltd

7. Device Description

The device is a surgical mask which can be described as non-sterile, single-use, 3 layer, flat-pleated style with ear loops and a nose piece. The outer layer of the surgical mask consists of blue nonwoven spunbond polypropylene and the inner layer consists of carded non-woven polyethylene/polyester. The middle layer consists of melt-blown polypropylene filter. The ear loops consists of 140D nylon and spandex elastic string not made with natural rubber latex. The nose piece is made with white galvanized iron with polyethylene coating.

8. Intended Use/ Indications for Use

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

9. Comparison of Technological Characteristics

Table 3 - Comparison of Technological Characteristics

Device	Proposed Device	Predicate Device	Remark
Manufacturer	CUSTOMFAB, INC.	Zhende Medical Co., Ltd	N/A
510(k) Number	K203012	K201729	N/A
Product Common Name	Surgical mask	Medical Face Mask	Similar
Product Code	FXX	FXX	Same
Classification	Class II 21 CFR 878.4040 Surgical apparel.	Class II 21 CFR 878.4040 Surgical apparel.	Same
	The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. This is a single use	The Medical 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 of the wearer to blood and	Same

	device, provided non-sterile.	body fluids. This is a single use, disposable device(s), provided non-sterile.	
Model	1 model of the level 1 surgical mask.	L1171801	N/A
Materials			
Device	Surgical Mask	Surgical Mask	Same
Outer Facing Layer	Blue non-woven spunbond polypropylene	Spun-bond polypropylene	Similar
Middle Layer	Melt-blown polypropylene	Melt blown polypropylene filter	Same
Inner Facing Layer	Non-woven polyester/polypropylene	Spun-bond polypropylene	Similar
Nose Piece	White galvanized steel with polyethylene coating	Malleable polypropylene with iron wire	Similar
Ear Loops	Nylon and spandex elastic String	Polyester and spandex	Similar
Color(s)	Blue and White	Blue	Similar
Specifications and Dimensions			
Dimension (width)	9.5 +/- 0.25 cm	9.5 +/- 1.0 cm	Similar
Dimension (length)	17.5 +/- 0.25 cm	18.0 +/- 1.0 cm	Similar
Mask Style			
Shape	Flat-pleated	Flat-pleated	Same
Design Features			
Ear Loops or Ties	Ear loops	Ear loops	Same
Nose Piece (if applicable)	Yes	Yes	Same
ASTM F2100 Level	Level 1	Level 1	Same
Use	Single Use	Single Use	Same
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Performance Data			
Standard	**Proposed Device**	**Predicate Device**	**Remarks**
Fluid Resistance Performance ASTM F1862	Fluid resistant, pass at 80 mmHg	Fluid resistant, pass at 80 mmHg	Same
Particulate Filtration Efficiency ASTM F2299/F2299M-03	≥95%	≥95%	Same
Bacterial Filtration Efficiency ASTM F2101-01(2019)	≥95%	≥95%	Same
Differential Pressure (Delta-P) ASTM F2100-19 (EN 14683)	<5.0 mmH_20/cm^2	<5.0 mmH_20/cm^2	Same
16 CFR Part 1610	Class 1	Class 1	Same
Biological Performance			

Standard	Proposed Device	Predicate Device	Remarks
Biocompatibility (ISO 10993)	Non-cytotoxic, Non-sensitizing, Non-irritating	Non-cytotoxic, Non-sensitizing, Non-irritating	Same

10. Performance Data

10.1 Non-Clinical Performance Data

The proposed Surgical Mask was tested to ASTM F2100-19 Level 1 requirements and pursuant to the FDA Guidance "Surgical Mask - Premarket Notification [510(k)] Submission".

Table 4- Performance Testing Summary

Test Item	Test Method	Pass Criteria	Results
Lot Number: K-1820-01 Sample Size: 32 surgical masks	Fluid Resistance Performance ASTM F1862	Fluid resistant, pass at 80 mmHg,	Pass, 29 of 32 Passed at 80 mmHg
Lot Number: J-0720-02 Sample Size: 32 surgical masks			Pass, 30 of 32 Passed at 80 mmHg
Lot Number: J-0920-03 Sample Size: 32 surgical masks			Pass, 29 of 32 Passed at 80 mmHg
Lot Number: J-0620-01 Sample Size: 32 surgical masks	Particulate Filtration Efficiency ASTM F2299/F2299M-03	≥95%	Pass, ≥97.6%
Lot Number: J-0720-02 Sample Size: 32 surgical masks			Pass, ≥98.8%
Lot Number: J-0920-03 Sample Size: 32 surgical masks			Pass, ≥96.8%
Lot Number: J-0620-01 Sample Size: 32 surgical masks	Bacterial Filtration Efficiency ASTM F2101-01(2019)	≥95%	Pass, ≥99.63%
Lot Number: J-0720-02 Sample Size: 32 surgical masks			Pass, ≥99.74%

Lot Number: J-0920-03 Sample Size: 32 surgical masks			Pass, ≥99.57%
Lot Number: J-0620-01 Sample Size: 32 surgical masks	Differential Pressure (Delta-P) ASTM F2100-19 (EN 14683)	<5.0 mmH_20/cm^2	Pass, Average 3.1 mmH_20/cm^2 All < 5.0 mmH_20/cm^2
Lot Number: J-0720-02 Sample Size: 32 surgical masks			Pass, Average 3.5 mmH_20/cm^2 All < 5.0 mmH_20/cm^2
Lot Number: J-0920-03 Sample Size: 32 surgical masks			Pass, Average 4.1 mmH_20/cm^2 All < 5.0 mmH_20/cm^2
Lot Number: J-0620-01 Sample Size: 32 surgical masks	16 CFR Part 1610	Class 1	Pass, 32 samples did not ignite
Lot Number: J-0720-02 Sample Size: 32 surgical masks			Pass, 32 samples did not ignite
Lot Number: J-0920-03 Sample Size: 32 surgical masks			Pass, 32 samples did not ignite

10.2 Clinical Performance Data

No Clinical study is included in this submission

11. Conclusion

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