March 2, 2023

Social Medical Supply LLC
℅ Mr. Jett Lee
Regulation Manager
Guangdong Jianda Medical Technology Co Ltd
906 Room, Longxiang Garden, Tianhe district
Guangzhou, Guangdong 510000
China

Re: K230093
Trade/Device Name: Disposable 4 Layers Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 12, 2023
Received: January 12, 2023

Dear Mr. Lee:

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,

Brent Showalter -S

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)*

K230093

Device Name

Disposable 4 layers surgical face mask

Indications for Use *(Describe)*

The Disposable 4 layers surgical face mask is intended to be worn by adults, and protects both patients and healthcare personnel from microorganisms, body fluids and particulate material transfer within a professional healthcare environment. The mask is designed for use in infection control practices to reduce the potential exposure to blood and body fluids. It is a single-use, disposable device(s), and 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

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a traditional 510(K) submission, and there were no prior submissions for the subject device.

1. Submitter's Information

Sponsor

- Company Name: SOCIAL MEDICAL SUPPLY LLC
- Address: 11528 Harry Hines Blvd, Suite A102 Dallas,TX 75229
- Tel：+1-214-416-9009 Fax:+1-214-416-9009
- Email: support@wellbefore.com
- Contact Person (including title): Shahzil Amin (General Manager)

Manufacturer

- Company Name: Jiangxi Xianmiyan Medical Technology Co., ltd
- Address： South side of the Ganda line of Xiangtian industrial Park, Jing'an County, Yichun City, Jiangxi Province，China
- Tel：+86-0754-87712777 Fax:+86-0754-87712777
- Email: finnick@wellbefore.com
- Contact Person (including title): Finnick Lin(General Manager)

Application Correspondent:

- Guangdong Jianda Medical Technology Co Ltd
- Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China
- Contact Person: Mr. Jett Lee
- Title: Regulation Manager
- Tel: +86 13512755282
- Email: jianda-lee@foxmail.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Classification/Common Name: Surgical Face Mask
- Trade Name: Disposable 4 layers surgical face mask
- Model: S1
- Review Panel: Surgical Apparel
- Product Code: FXX

- Regulation Number: 878.4040
- Regulation Class: 2

3. Predicate Device Information

- 510(k) number: K221272
- Sponsor: Shandong Xingyu Gloves Co., Ltd.
- Classification/Common Name: Surgical Face Mask
- Trade Name: Surgical Face Mask
- Model: Ear Loop
- Review Panel: Surgical Apparel
- Product Code: FXX
- Regulation Number: 878.4040
- Regulation Class: 2

4. Device Description

The WellBefore 4 Layers disposable surgical mask is an adult-sized surgical mask equipped with earloops, designed to cower the user's nose and mouth. The surgical face masks are consists of Outer Layer(Non-woven fabric made from spunbond polypropylene), Second Layer(melt-blown filtration fabric made from polypropylene), Third Layer(Electrostastic cotton made from ethylene-propylene side by side), Inner Layer(Non-woven fabric made from spunbond polypropylene), Nose Bridge(Double-wirenosepinmade by polypropylene, and Ear loops(Polyster Fiber and Spandex). The mask acts as a physical barrier from fuids and particulate materials, and providing a level 3 barrier. It is a single-use, disposable device(s) , provided non-sterile.

5. Intended Use / Indications for Use

The Disposable 4 layers surgical face mask is intended to be worn by adults, and protects both patients and healthcare personnel from microorganisms, body fluids and particulate material transfer within a professional healthcare environment. The mask is designed for use in infection control practices to reduce the potential exposure to blood and body fluids. It is a single-use, disposable device(s) , provided non-sterile.

6. Test Summary

1)Non-clinical Test performed on the proposed device

The Surgical Mask has been evaluated for its safety and performance by lab bench testing as following:

- Three lots tested according to ASTM F2100-19 standard

Performance requirement and test method recommended in ASTM F2100		
Item	**Performance requirement**	**Test method**
Fluid Resistance Performance	29 out of 32 pass at 160mmHg	ASTM F1862
Particulate Filtration Efficiency	⩾98%	ASTM F2299

Bacterial Filtration Efficiency	⩾98%	ASTM F2101
Differential Pressure (Delta P)	< 6.0 mmH_2O/cm^2	EN 14683:2019, Annex C
Flammability	Class 1	16 CFR 1610

- Biocompatibility test according to ISO 10993-1 standard
  1) Cytotoxicity Test with MTT Method according to ISO 10993-5
  2) Skin Irritation Test with test method: 0.9% Sodium Chloride Injection Extract and Soybean Oil Extract according to ISO 10993-10
  3) Skin Sensitization with test method: 0.9% Sodium Chloride Injection Extract and Soybean Oil Extract according to ISO 10993-10

Performance testing result

Performance Testing Items	Test result	Criteria	Remark
Fluid Resistance Performance ASTM F1862	3 lots with at least 29 out of 32 passing at 160mmHg (level 3)	3 lots with at least 29 out of 32 passing at 160mmHg (level 3)	Pass
Particulate Filtration Efficiency ASTM F2299	3 lots at ≥98%	3 lots at ≥98%	Pass
Bacterial Filtration Efficiency ASTM F2101	3 lots at 99.9%	3 lots at ≥98%	Pass
Differential Pressure (Delta P) EN 14683:2019, Annex C	3 lots passing at at <6.0 mmH_2O/cm^2	3 lots passing at <6.0 mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1 Non Flammable	Pass
Biocompatibility	Cytotoxicity/Irritation/Sensitization according to ISO10993-5; ISO10993-10	Cytotoxicity/Irritation/Sensitization according to ISO10993-5; ISO10993-10	Pass

2) Clinical Test Conclusion

No clinical study is included in this submission.

7. Summary of Technological Characteristic

The technological characteristics, features, specifications, materials, and intended use of Surgical Mask is similar to the predicate device quoted above. The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Device	Proposed Device	Predicate Device	Comparison
510(K)	Apply	K221272	--
Sponsor	SOCIAL MEDICAL SUPPLY LLC	Shandong Xingyu Gloves Co., Ltd.	--
Manufacturer	Jiangxi Xianmiyan Medical	Shandong Xingyu Gloves Co., Ltd.	--

		Technology Co., ltd		
Product Name		Disposable 4 layers surgical face mask	Surgical Face Mask	--
Classification		Class II, FXX (21 CFR878.4040)	Class II, FXX (21 CFR878.4040)	Same
Intended Use		The Disposable 4 layers surgical face mask is intended to be worn by adults, and protects both patients and healthcare personnel from microorganisms, body fluids and particulate material transfer within a professional healthcare environment. The mask is designed for use in infection control practices to reduce the potential exposure to blood and body fluids. It is a single-use, disposable device(s) , provided non-sterile.	The Medical 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 a single use, disposable device(s), provided non-sterile.	substantially equivalent
Material	Outer Layer	Non-woven fabric (spunbond PP)	Non-woven fabric	Same
	Middle Layer	Second Layer: Melt blown polypropylene filter Third Layer: Electrostastic cotton made from ethylene-propylene	Melt-blown Non-woven fabric	Different Note1
	Inner Facing Layer	Non-woven fabric	Non-woven fabric	Same
	Noise Piece	Malleable polyethylene wire	Metal Core Plastic (Iron wire & Polypropylene)	Same
	Ear Loops	Polyster and Spandex	Polyster and Spandex	Same
Color		Blue	Blue, Black	Different Note2
Dimension		17.7cm*9.5cm, ±1cm tolerance	17.5cm*9.5cm, ±0.5cm tolerance	Different Note2
OTC Use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
Performance Testing (ASTM F2100)		Level 2 & 3	Level 2 & 3	Same
Fluid Resistance Performance ASTM F1862		29 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg	Different Note3
Particulate Filtration Efficiency ASTM F2299		⩾98%	⩾98%	Same

Bacterial Filtration Efficiency ASTM F2101	⩾98%	⩾98%	Same
Differential Pressure (Delta P)	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	Same
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1 Non Flammable	Same
Biocompatibility	Meet ISO10993 ,proved noncytotoxicity, non-irritating and non-sensitizing	Meet ISO10993 ,proved noncytotoxicity, non-irritating and non-sensitizing	Same

Comparison in Detail(s):

Note 1:

The difference in the middel layer material and layer numbers does not raise additional questions for safety and effectiveness. The biocompatibility tests were conducted to both components to ensure their compliance to the ISO10993-5 and ISO10993-10. Performance tests were in accordance with ASTM F2100 standard. There is no new risk generated from the difference of the material and layer number .

Note 2:

The difference in the dimensions and colors does not raise additional questions for safety and effectiveness. The dimensions of proposed device is design for adults. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

Note 3:

The difference in Fluid Resistance Performance ASTM F1862 is does not raise additional questions for safety and effectiveness.

8. Summary for clinical test

Clinical performance is not deemed necessary.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed devices identified.