



January 10, 2022

Liaoning Shengjingtang Biotechnology Co., Ltd.
Hai Luan
CEO
Huamei (Dalian) Health Industry Co., Ltd
RM. 956 NO. 60-2 Haixing St, Dalian Tax-Free Zone
Dalian, 116001
China

Re: K211260
Trade/Device Name: Sheng Jing Tang Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 28, 2021
Received: December 1, 2021

Dear Hai Luan:

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 Clarence W. Murray, III, Ph.D.
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

Indications for Use

510(k) Number (if known)
K211260

Device Name
Sheng Jing Tang Surgical Mask

Indications for Use (Describe)

Sheng Jing Tang Surgical Mask is intended for use in healthcare settings, procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device is indicated to be over-the-counter use. Adult only. The device is disposable and is indicated for single use. The device is not provided 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
PRASStaff@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

This 510(k) Summary is being submitted in accordance with the requirements of Title 21. CFR Section 807.92.

The assigned 510(k) number: K211260

Date of Preparation: 11/02/2021

1. Contact Information

1.1 Applicant

Applicant Name: Liaoning Shengjingtang Biotechnology Co., Ltd.

Address: 123-11 Huishan St, Shenbei New District, Shenyang, Liaoning, China 110141

Contact Person: Li Ke

Title: General Manager

Telephone: +86-135-914-61018

Email: 174866792@qq.com

1.2 Consultant

Company: Huamei (Dalian) Health Industry Co., Ltd

Address: RM. 956 NO.60-2 Haixing St, Dalian Tax-Free Zone, China, 116001

Contact Person: Luan Hai

Telephone: +1 503-559-0930

Email: usfdahuamei@hotmail.com

2. Device Information

Trade Name: Sheng Jing Tang Surgical Mask

Common Name: Surgical Face Mask

Regulatory information:

Classification Name: Mask, Surgical

Classification: II

Product Code: FXX

Regulation Number: 21 CFR 878.4040

Review Panel: General Hospital

3. Legally Marketed Primary Predicate Device

Product name: Avianz® Surgical Face Mask

510(k) Number: K200847

Product Code: FXX

Manufacture: MEXPO INTERNATIONAL INC.

4. Indication For Use

Sheng Jing Tang Surgical Mask is intended for use in healthcare settings, procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device is indicated to be over-the-counter use. Adult only. The device is disposable and is indicated for single use. The device is not provided sterile.

5. Device Description

The Sheng Jing Tang Surgical Masks are composed of 3-layers and are flat-pleated provided blue color, the mask materials consist of an outer layer (Spun-bond polypropylene), Inner layer (Spun-bond polypropylene),

Middle Layer filter (Polypropylene Melt-blown Cloth), Ear-loops (Spandex + Nylon, Ear Loops way for wearing) and Nose piece (a Polyethylene + Galvanized Iron wire nosepiece to provide a firm fit over the nose and then to secure the mask over the users' mouth and face). The Sheng Jing Tang Surgical Masks are single use, disposable device, adult only, provided non-sterile.

6. Substantially Equivalent (SE) Comparison

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Product Code	FXX	FXX	Same
Regulation	21 C.F.R Section 878.4040	21 C.F.R Section 878.4040	Same
Classification	Class II	Class II	Same
Intended use	Sheng Jing Tang Surgical Mask is intended for use in healthcare settings, procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device is indicated to be over-the-counter use. Adult only. The device is disposable and is indicated for single use. The device is not provided sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from the 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(s) provided non-sterile.	Same
Mask Style	Flat-pleated, earloop, 3 layers	Flat-pleated, earloop, 3 layers	Same

6.1 Material Used

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Middle layer	Polypropylene Melt-blown cloth	Melt blown polypropylene filter	Same
Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Earloop	Spandex + Nylon	Polyester	*Different ¹
Nose piece	Polyethylene + Galvanized Iron wire	Malleable aluminum wire	*Different ¹

6.2 Design Features

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Use Environment	OTC, or Healthcare or related settings	OTC, or Healthcare or related settings	Same
Single-use/ Multiple-use	Single-use	Single-use	Same
Color	Blue	Blue	Same

6.3 Sterility

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Sterilization	No-Sterile	No-Sterile	Same

6.4 Dimension

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Length	17.5±0.875cm	17.5±1cm	*Different ¹
Width	9.5±0.475cm	9.5±1cm	*Different ¹

6.5 Effectiveness / Performance

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Resistance to Penetration by Synthetic blood 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)	Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: 32 Out of 32 pass at 120 mmHg Lot 2: 32 Out of 32 pass at 120 mmHg Lot 3: 32 Out of 32 pass at 120 mmHg	≥ 30 Out of 32 pass at 120 mmHg	Same
Particulate Filtration Efficiency ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of	Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: ≥ 98.24%	≥ 99.9%	*Different ²

Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres	<p>Lot 2: $\geq 98.78\%$</p> <p>Lot 3: $\geq 98.82\%$</p>		
Bacterial Filtration Efficiency ASTM F2101-2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	<p>Pass (96/96) 32 Samples Each from 3 non-consecutive lots</p> <p>Lot 1: $\geq 99.9\%$</p> <p>Lot 2: $\geq 99.9\%$</p> <p>Lot 3: $\geq 99.9\%$</p>	$\geq 98\%$	*Different ³
Differential Pressure EN 14683:2019 Medical face masks- Requirements and test methods	<p>Pass (96/96) 32 Samples Each from 3 non-consecutive lots</p> <p>Lot 1: Average 5.56 mmH₂O/cm²</p> <p>Lot 2: Average 5.51 mmH₂O/cm²</p> <p>Lot 3: Average 4.97 mmH₂O/cm²</p> <p>(EN 14683:2019, Annex C and ASTM F2100-20)</p>	3.0 mmH ₂ O/cm ² (MILM-36954C)	*Different ⁴
Flammability 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections	<p>Class 1 Pass (96/96) 32 Samples Each from 3 non-consecutive lots</p> <p>Lot 1: Class 1 Pass</p> <p>Lot 2: Class 1 Pass</p> <p>Lot 3: Class 1 Pass</p>	Class 1	Same

6.6 Safety

Comparison Items	Sheng Jing Tang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
In Vitro Cytotoxicity Test ISO 10993-5: 2009	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Same
Skin Irritation Test ISO 10993-10:2010	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Same
Skin Sensitization Test ISO 10993-10:2010	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Same
Flammability	Class 1	Class 1	Same

***Different¹** The difference in the materials, colors, and sizes do not raise additional questions for the device's safety and effectiveness. The subject devices' biocompatibility evaluation test and performance test were performed on the final finished device, including all construction materials, color and sizes. The test results indicated that pass the requirements.

***Different²** The test was performed in accordance with ASTM F2299-03 (Reapproved 2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres, to determine the Particle Filtration Efficiency. Here, Sheng Jing Tang Surgical Mask compares to Predicate Device that results are very closed by statistics. Thus, this difference does not substantially affect equivalence between the Sheng Jing Tang Surgical Mask and predicate devices.

***Different³** The test was performed in accordance with 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 to determine the bacterial filtration efficiency (BFE) of the test article. Here, Sheng Jing Tang Surgical Mask compares to Predicate Device that results are very closed by statistics. Thus, this difference does not substantially affect equivalence between the Sheng Jing Tang Surgical Mask and predicate devices.

***Different⁴** The test result for different pressure for the proposed device is different from predicate devices. The differential pressure test standard has been updated to EN14683:2019, Annex C in ASTM F2100:2020. The differential pressure test of the proposed device was conducted according to EN14683:2019, Annex C, and the test result demonstrates that the differential pressure of the proposed device meets the requirements of level 2 specified in ASTM F2100:2020. Thus, this difference does not substantially affect equivalence between the Sheng Jing Tang Surgical Mask and predicate devices.

7. Nonclinical Test

Nonclinical tests were conducted to verify that the proposed device met all design specifications, as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

7.1 Performance Test:

A bench test was conducted on Sheng Jing Tang Surgical Mask for the proposed device to determine

substantial equivalence. The bench tests include the following tests:

Performance Test	Sheng Jing Tang Surgical Mask	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862-17	Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: 32 Out of 32 pass at 120 mmHg Lot 2: 32 Out of 32 pass at 120 mmHg Lot 3: 32 Out of 32 pass at 120 mmHg	≥29 of 32 pass at 120 mmHg	Passed
Particulate Filtration Efficiency ASTM F2299-17	Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: ≥ 98.24% Lot 2: ≥ 98.78% Lot 3: ≥ 98.82%	≥ 98%	Passed
Bacterial Filtration Efficiency ASTM F2101-19	Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: ≥ 99.9% Lot 2: ≥ 99.9% Lot 3: ≥ 99.9%	≥ 98%	Passed
Differential Pressure (Delta P) EN 14683:2019, Annex C and ASTM F2100-20.	Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: Average 5.56 mmH ₂ O/cm ² Lot 2: Average 5.51 mmH ₂ O/cm ² Lot 3: Average 4.97 mmH ₂ O/cm ² (EN 14683:2019, Annex C and	<6.0 mmH ₂ O/cm ²	Passed

	ASTM F2100-20)		
Flammability 16 CFR 1610	Class 1 Pass (96/96) 32 Samples Each from 3 non-consecutive lots Lot 1: Class 1 Pass Lot 2: Class 1 Pass Lot 3: Class 1 Pass	Class 1	Passed

7.2 Biocompatibility Evaluation and Test

Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance supports that the subject devices are biocompatible.

The biocompatibility test includes the following tests:

7.2.1 In Vitro Cytotoxicity Test (ISO 10993-5: 2009)

7.2.2 Skin Irritation Test (ISO 10993-10:2010)

7.2.3 Skin Sensitization Test (ISO 10993-10:2010)

Biocompatibility Evaluation and Test	Purpose	Acceptance Criteria	Result
7.2.1 In Vitro Cytotoxicity Test ISO 10993-5: 2009	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Non-cytotoxic.	Passed
7.2.2 Skin Irritation Test ISO 10993-10:2010	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Non-irritating.	Passed
7.2.3 Skin Sensitization Test ISO 10993-10:2010	ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Non-sensitizing	Passed

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests that demonstrate that Sheng Jing Tang Surgical Mask is as safe, as effective and performs as well as the legally marketed device identified in this submission.