September 1, 2021

Welspun India Limited
% Manoj Zacharias
US Agent
Liberty Management Group Limited
75 Executive Drive, Suite 114
Aurora, Illinois 60504

Re: K211536
Trade/Device Name: Welspun Health Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 3, 2021
Received: August 6, 2021

Dear Manoj Zacharias:

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

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)*
K211536

Device Name
Welspun Health Surgical Mask

Indications for Use *(Describe)*
The Welspun Health Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical face masks are intended for use in infection control practices to reduce the potential exposure to blood & body fluid. This device is disposable, non-sterile and for single use only.

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 (K211536)

[AS REQUIRED BY 21CFR807.92]

I. APPLICANT INFORMATION

Submitter's Name and Address	Welspun India Limited (Advanced Textiles Division), Survey No. 719, Village: Versamedi, Tal: Anjar, District: Kutch , Gujarat, 370110, India
Fax	+91 2836 279010
Contact person	Mr. Satyapriya Dash
Designation	AGM, Head TQM & PD
Contact Number	+91-7359072111
Contact E-mail	satyapriya_dash@welspun.com, care@welspun.com
Date of Summary Prepared	03 August 2021

II. DEVICE DETAILS

Device Trade Name	Welspun Health Surgical Mask
Device Common Name	Surgical Face Mask
Model(s)	WHSM002ELB, WHSM002ELW
Device Classification name	Mask, Surgical
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

Welspun India Limited
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T: +91 226613600 / 2490 8000 Fax: +91 22 2490 8020
E-mail: nonwovens@welspun.com Website: www.welspun.com

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T: +91 260 2437437 Fax: +91 260 2437088

Registered Office & Plant II : Survey No. 719, Village: Varsamedi, Tal : Anjar, District : Kutch , Gujarat - 370110, India.
T: +91 2836 661111 Fax: +91 2836 279010

Corporate Identification No.: L17110GJ1985PLC033271

III. PREDICATE DEVICE DETAILS

Device Trade Name	Disposable Medical Surgical Mask
Device Manufacturer Name	Improve Medical (HuNan) Co., Ltd.
510(k) Number	K202511
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

IV. DEVICE DESCRIPTION

Welspun Health Surgical Mask is a surgical face mask identified by Regulation 21 CFR 878.4040 under FDA product code, FXX. This medical device is offered in two colors – medical blue (Model No.: WHSM002ELB) and white (Model No.: WHSM002ELW).

The Welspun Health Surgical Mask is three-layer, flat pleated mask. It is made up of three layers of non-woven polypropylene on automatic mask making machine using the ultrasonic sealing technology.

The inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The proposed device is held in place over the user's mouth and nose by two elastic ear loops welded to the face mask. The ear loops are made of round knitted elastic band.

The nose strip contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of polypropylene coated single core aluminium wire.

The surgical masks are single-use, disposable devices, provided non-sterile.

V. INDICATIONS FOR USE

The Welspun Health Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical face masks are intended for use in infection control practices to reduce the potential exposure to blood & body fluid. This device is disposable, non-sterile and for single use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K211536	K202511	-
2.	Manufacturer	Welspun India Limited	Improve Medical (HuNan) Co., Ltd.	-
3.	Common Name	Surgical face mask	Surgical face mask	Same
4.	Classification Name	Mask, Surgical	Mask, Surgical	Same
5.	Classification and Regulation number	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040	Same
6.	Product Code	FXX	FXX	Same
7.	Indication For Use	The Welspun Health Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical face masks are intended for use in infection control practices to reduce the potential exposure to blood & body fluid. This device is disposable, non-sterile and for single use only.	The Disposable 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 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
8.	Model specifications	3 ply flat pleated masks with ear loops	Ear loops, Flat Pleated, 3 layers	Same
Materials				
9.	Outer layer	Spun bond polypropylene	Spun bond polypropylene	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
10.	Filter layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
11.	Inner layer	Spun bond polypropylene	Spun bond polypropylene	Same
12.	Nose strip	Polypropylene coated single core aluminium wire	Polyethylene coated steel wire	Different(1)
13.	Ear loops	Knitted elastic band	Polyester	Different(2)
14.	Mask style	Flat pleated	Flat pleated	Same
15.	Mask color	Medical Blue, White	Blue	Different(3)
16.	Dimensions	Length- 175 ± 5 mm Width- 95 ± 5 mm Ear Loop Length: 160±10mm	Length-17.5 ± 0.2 cm Width- 9.5 ± 0.2 cm	Similar
17.	OTC Use	Yes	Yes	Same
18.	Sterility	Non-sterile	Non-sterile	Same
19.	Usage	Single use, disposable	Single use, disposable	Same
20.	ASTM F2100 Level	Level 3	Level 3	Same
Non Clinical Testing				
21.	Fluid resistance	Pass at 160 mmHg	32 out of 32 pass at 160 mmHg	Similar
22.	Flammability	Class I	Class 1	Same
23.	Particulate Filtration Efficiency (PFE)	>99%	Pass at 98.6%	Similar
24.	Bacterial Filtration Efficiency (BFE)	>98%	Pass at 99.9%	Similar
25.	Differential pressure (ΔP)	< 6.0 mm H_20/cm^2	Pass at 3.5 mmH_20/cm^2	Similar
26.	Biocompatibility Testing	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.	Same

VII. JUSTIFICATION FOR DIFFERENCES

The difference is mainly observed in the nose strip, ear loop and color. The differences between proposed device and the predicate device are discussed in detail below and the justification for these are included:

Different(1): The proposed device is using nose strip of polypropylene coated single core aluminium wire whereas the predicate device is using polyethylene coated steel wire.

Different(2): In the proposed device ear loops are made using knitted elastic band not made from natural rubber latex. But, in the predicate device the ear loops are made of polyester.

Different(3): The proposed device is available in two colors – medical blue (Model No.: WHSM002ELB) and white (Model No.: WHSM002ELW) whereas the predicate device is available only in one color- blue.

Justification: Biocompatibility testing in accordance with ISO 10993-1 and performance testing as per ASTM F2100 have been conducted on the final finished device. The proposed device meets the acceptance criteria for level 3 classification as per requirements of performance standard ASTM F2100 and also passes the biocompatibility tests. The safety and effectiveness of Welspun Health Surgical Mask has been demonstrated through the different non-clinical testing performed on these masks. Therefore, the differences between proposed device and the predicate device does not raise any issue regarding the safety or effectiveness of Welspun Health Surgical Mask.

VIII. PERFORMANCE DATA

A. Non- Clinical Data

Performance Tests

Welspun Health Surgical Mask is subjected to the following performance tests according to the requirements provided in the guidance **Surgical Masks - Premarket Notification [510(k)] Submissions** and is found to be efficient with respect to its intended use:

- Fluid resistance
- Bacterial filtration efficiency
- Particulate filtration efficiency
- Differential pressure
- Flammability

The performance testing of the proposed device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant methods cited below:

ASTM F2100-19	:	Standard Specification for Performance of Materials Used in Medical Face Masks
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.
ASTM F2299/F2299M - 03(2017)	:	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
EN 14683 (Annex C): 2019	:	Medical Face Masks – Requirements And Test Methods
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)
16 CFR 1610	:	Standard for the Flammability of clothing textiles

The summary of performance testing on the proposed device models WHSM002ELB and WHSM002ELW are given in the table 2 below.

Table 2: Performance Testing Summary

Sl. No	**Test Performed**	**Proposed Device**		**Acceptance criteria for Level 3 Classification as per ASTM F2100 Requirements**	**Result**
		Model No. : WHSM002ELB	**Model No. : WHSM002ELW**		
1.	Fluid resistance ASTM F1862/ F1862M-17	Pass at 160 mmHg	Pass at 160 mmHg	29 out of 32 Pass at 160 mmHg	Pass
2.	Particulate Filtration Efficiency (PFE) ASTM F2299 / F2299M - 03(2017)	>99%	>99%	≥ 98%	Pass
3.	Bacterial Filtration Efficiency (BFE) ASTM F2101-19	>98%	>98%	≥ 98%	Pass
4.	Differential pressure (ΔP) EN 14683 (Annex C): 2019	< 5.0 mm H_20/cm^2	< 6.0 mm H_20/cm^2	< 6.0 mm H_2O/cm^2	Pass
5.	Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Pass

Biocompatibility

The following tests is performed on the Welspun Health Surgical Mask as per requirements in guidance **Surgical Masks - Premarket Notification [510(k)] Submissions** and the FDA guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing** and is found to be safe with respect to its intended use:

- In vitro Cytotoxicity
- Skin irritation
- Skin Sensitization

These tests are performed according to **ISO 10993-1:2018**, Biological Evaluation of Medical Devices - Part 1, Evaluation and Testing within a Risk Management Process.

The biocompatibility testing of the proposed device was conducted to adequately demonstrate the safety of the device in accordance with the relevant methods cited below:

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.

Table 3: Biocompatibility Test Summary

Sl. No	Test Performed	Standard	Proposed Device		Result
			Model No. : WHSM002ELB	Model No. : WHSM002ELW	
1.	Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Non-cytotoxic	Pass
2.	Irritation	ISO 10993-10:2010	Non-irritating	Non-irritating	Pass
3.	Sensitization	ISO 10993-10:2010	Non-sensitizing	Non-sensitizing	Pass

B. Clinical Test Data

Clinical study was not conducted as clinical data is not needed for surgical mask.

IX. 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.