June 28, 2022

Magnum Health And Safety Pvt Ltd
% Manoj Zacharias
US Agent
Liberty Management Group Ltd.
75 Executive Drive, Suite 114
Aurora, Illinois 60504

Re: K220670
Trade/Device Name: Magnum
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 31, 2022
Received: June 2, 2022

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,

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)*
K220670

Device Name
Magnum

Indications for Use *(Describe)*
When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. The face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. APPLICANT INFORMATION

Submitter's Name	Magnum Health And Safety Pvt Ltd
Submitter's Address	Unit No. 21, 22, 23, Supreme Industrial Estate, Lucky Compound, Near Bhajanlal Dairy, Chinchoti Naka, Village Devdal, Taluka - Vasai, Dist - Palghar, Maharashtra, India - 401208
Name of Contact Person	Mr. Rakesh Bhagat
Designation	Director
Contact Number	+91 9820050482
Contact E-mail	rakesh@magnumohs.com
Date of Summary Prepared	11 February 2022

II. DEVICE DETAILS

Device Trade Name	Magnum
Device Common Name	Surgical Face Mask
Model(s)	2200 (Level 2, 3ply with ear loop) 2300 (Level 3, 3ply with ear loop) 1200 (Level 2, 3ply with tie back) 1300 (Level 3, 3ply with tie back)
Device Classification name	Mask, Surgical
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

III. PREDICATE DEVICE DETAILS

Device Trade Name	Surgical Face Mask
Device Manufacturer Name	Anhui Tiankang Medical Technology Co.,Ltd.
Model(s)	**Model No.** — **Model Description** WKKZ.R.LEVEL1-001 — Level 1, Ear loop, Flat pleated, 3 layers WKKZ.R.LEVEL2-001 — Level 2, Ear loop, Flat pleated, 3 layers WKKZ.R.LEVEL3-001 — Level 3, Ear loop, Flat pleated, 3 layers WKKZ.J.LEVEL1-001 — Level 1, Tie-on, Flat pleated, 3 layers WKKZ.J.LEVEL2-001 — Level 2, Tie-on, Flat pleated, 3 layers WKKZ.J.LEVEL3-001 — Level 3, Tie-on, Flat pleated, 3 layers
510(k) Number	K212368
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

IV. DEVICE DESCRIPTION

Magnum is a surgical face mask identified by Regulation 21 CFR 878.4040 under FDA product code, FXX. This medical device is offered in a single color – blue.

The inner and outer layers are made of spun-bond polypropylene non-woven fabric, and the middle layer is made of melt blown filter media. The nose wire 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 PVC coated aluminum wire.

The model 2200 is level 2 surgical face mask and the model 2300 is level 3 surgical face mask. Both these models are provided with ear loops to hold and fit the face mask in place over the user's mouth and nose. The ear loops are made of knitted elastic.

The model 1200 is level 2 surgical face mask and the model 1300 is level 3 surgical face mask. Both these models are provided with tie back to hold and fit the face mask in place over the user's mouth and nose. The tie back string is made of spun-bond polypropylene non-woven fabric.

The dimensions of the test item are: length- 172 ± 3 mm and width- 95 ± 3 mm.

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

V. INTENDED USE

The face masks are intended for use in infection control practices to reduce the potential exposure to blood and 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		K212368	-
2.	Manufacturer	Magnum Health And Safety Pvt Ltd	Anhui Tiankang Medical Technology 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.	Indications For Use	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. The face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This device is disposable, non-sterile and for single use only.	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 blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
8.	Model specifications	2200 (Level 2, Ear Loops, Flat Pleated, 3 layers) 2300 (Level 3, Ear Loops, Flat Pleated, 3 layers) 1200 (Level 2, Tie back, Flat Pleated, 3 layers) 1300 (Level 3, Tie back, Flat Pleated, 3 layers)	WKKZ.R.LEVEL2-001 (Level 2, Ear loop, Flat pleated, 3 layers) WKKZ.R.LEVEL3-001 (Level 3, Ear loop, Flat pleated, 3 layers) WKKZ.J.LEVEL2-001 (Level 2, Tie-on, Flat pleated, 3 layers) WKKZ.J.LEVEL3-001 (Level 3, Tie-on, Flat pleated, 3 layers)	Same
Materials				
9.	Outer layer	Spun bond polypropylene	Spun-bond polypropylene	Same
10.	Filter layer	Melt blown filter media	Melt blown polypropylene filter	Same
11.	Inner layer	Spun bond polypropylene	Spun-bond polypropylene	Same
12.	Nose wire	PVC coated aluminum wire	PP coated steel wire	Different[1]
13.	Ear loop	**For model(s): 2200 and 2300** Ear Loop: Knitted elastic	**For model(s): WKKZ.R.LEVEL2-001 and WKKZ.R.LEVEL3-001** Ear Loop: Nylon and spandex	Different[2]
14.	Tie back	**For model(s): 1200 and 1300** Tie back: Spun-bond polypropylene non-woven fabric	**For model(s): WKKZ.J.LEVEL2-001 and WKKZ.J.LEVEL3-001** Tie back: PP nonwoven	Same
15.	Mask color	Blue	Blue	Same
16.	Dimensions	Length- 172 ± 3 mm Width- 95 ± 3 mm	Length- 175 ± 5 mm Width- 95 ± 2.85 mm	Similar
17.	OTC Use	Yes	Yes	Same
18.	Sterility	Non-sterile	Non-sterile	Same
19.	Reusability	Single use	Single use	Same
20.	ASTM F2100 Level	Level 2 & 3	Level 2 & 3	Same

Sl. No	Features compared	Proposed Device		Predicate Device		Result
Non Clinical Testing						
21.	Fluid resistance	Level 2 models	Pass at 120 mmHg	Level 2 models	Pass at 120 mmHg	Same
		Level 3 models	Pass at 160 mmHg	Level 3 models	Pass at 160 mmHg	Same
22.	Flammability	All models – Class I		All models – Class I		Same
23.	Particulate Filtration Efficiency (PFE)	Level 2 models	Pass at >98%	Level 2 models	Pass at ≥98%	Same
		Level 3 models	Pass at >98%	Level 3 models	Pass at ≥98%	Same
24.	Bacterial Filtration Efficiency (BFE)	Level 2 models	Pass at >98%	Level 2 models	Pass at ≥98%	Same
		Level 3 models	Pass at >98%	Level 3 models	Pass at ≥98%	Same
25.	Differential pressure (ΔP)	Level 2 models	Pass at < 6.0 mmH20/cm2	Level 2 models	Pass at < 6.0 mmH20/cm2	Same
		Level 3 models	Pass < 6.0 mmH20/cm2	Level 3 models	Pass < 6.0 mmH20/cm2	Same
26.	Biocompatibility Testing: In vitro cytotoxicity	Non-cytotoxic under the conditions of the study		All models non-cytotoxic under the conditions of the study		Same
27.	Biocompatibility Testing: Skin Irritation	Non-irritating under the conditions of the study		All models non-irritating under the conditions of the study		Same
28.	Biocompatibility Testing: Skin Sensitization	Non-sensitizer under the conditions of the study		All models non-sensitizer under the conditions of the study		Same

VII. JUSTIFICATION FOR DIFFERENCES

The difference is mainly observed in the nose wire and ear loop. The differences between proposed device and the predicate device are discussed in detail below and the justifications are included:

Different[1]: The proposed device is using nose wire of PVC coated aluminum wire whereas the predicate device is using nose wire made of PP coated steel wire.

Different[2]: In the proposed device ear loop for models 2200 and 2300 is made of knitted elastic. But, in the predicate device the ear loop is made of nylon and spandex.

Justification: The safety and effectiveness of Magnum has been demonstrated through the different performance and biocompatibility 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 Magnum.

VIII. PERFORMANCE DATA

A. Non- Clinical Data

Performance Tests

Magnum 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 safe and 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 1300 and 2300 are given in the table 2 and the summary of performance testing on the proposed device models 1200 and 2200 are given in the table 3.

Table 2: Performance Testing Summary for Models 1300 and 2300

Sl. No	Test Performed	Proposed Device		Acceptance criteria for Level 3 Classification	Result
		Model 1300	Model 2300		
1.	Fluid resistance ASTM F1862/ F1862M-17	Pass at 160 mmHg	Pass at 160 mmHg	Pass at 160 mmHg	Pass
2.	Particulate Filtration Efficiency (PFE) ASTM F2299 / F2299M - 03(2017)	> 98%	> 98%	≥ 98%	Pass
3.	Bacterial Filtration Efficiency (BFE) ASTM F2101-19	> 98%	> 98%	≥ 98%	Pass
4.	Differential pressure (ΔP) EN 14683 (Annex C): 2019	< 3.0 mmH_2O/cm^2	< 3.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	Pass
5.	Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Pass

Table 2: Performance Testing Summary for Models 1200 and 2200

Sl. No	Test Performed	Proposed Device		Acceptance criteria for Level 2 Classification	Result
		Model 1200	Model 2200		
1.	Fluid resistance ASTM F1862/ F1862M-17	Pass at 120 mmHg	Pass at 120 mmHg	Pass at 120 mmHg	Pass
2.	Particulate Filtration Efficiency (PFE) ASTM F2299 / F2299M - 03(2017)	> 98%	> 98%	≥ 98%	Pass
3.	Bacterial Filtration Efficiency (BFE) ASTM F2101-19	> 98%	> 98%	≥ 98%	Pass
4.	Differential pressure (ΔP) EN 14683 (Annex C): 2019	< 3.0 mmH_2O/cm^2	< 3.0 mmH_2O/cm^2	< 6.0 mm H_2O/cm^2	Pass
5.	Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Pass

Biocompatibility

The materials used in the **Magnum** are biocompatible based on the biocompatibility tests mentioned in the guidance **Surgical Masks - Premarket Notification [510(k)] Submissions**:

- 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 10993-23: 2021 : Biological Evaluation Of Medical Devices - Part 23: Tests For Irritation.

ISO 10993-10: 2021 : Biological Evaluation Of Medical Devices - Part 10: Tests For Skin Sensitization.

Table 3: Biocompatibility Test Summary

Sl. No	Test Performed	Standard	Proposed Device		Result
			Model 2300	Model 1300	
1.	In-vitro Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Non-cytotoxic	Pass
2.	Skin Irritation	ISO 10993-23:2021	Non-irritating	Non-irritating	Pass
3.	Skin Sensitization	ISO 10993-10:2021	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.