May 7, 2021

Qingdao Hainuo Biological Engineering Co., Ltd.
Raphael Wang
Director
Industrial Park, Jiangshan Town, Laixi City
Qingdao, Shandong 266000
China

Re: K210218
Trade/Device Name: SURGICAL MASK, Model Name:C015
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 26, 2021
Received: April 5, 2021

Dear Raphael Wang:

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,

Clarence W. Murray, III, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210218

Device Name
SURGICAL MASK, Model Name:C015

Indications for Use *(Describe)*
The "SURGICAL MASK" is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The "SURGICAL MASK" is intended for use in infection control practices to reduce the potential exposure to blood and body fluids.
This is a single use, disposable 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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K210218 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 29 April 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Qingdao Hainuo Biological Engineering Co., Ltd.
Address:	Industrial Park, Jiangshan Town, Laixi City
	Qingdao, Shandong, 266000 China
Contact person:	Raphael Wang
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2. Device Identification

Trade/Device Name:	SURGICAL MASK, Model Name: C015
Common name:	Mask, Surgical
Regulation Number:	878.4040
Regulation Name:	Surgical apparel
Regulation Class:	Class II
Panel:	General Hospital
Product Code:	FXX

3. Predicate Device

510(K) number:	K200923
Device Name:	Single-use Surgical Mask
Manufacturer:	BYD Precision Manufacturer Co.Ltd.
Common name	Mask, Surgical
Regulation Number:	878.4040
Regulation Name:	Surgical apparel
Regulation Class:	Class II
Panel:	General Hospital
Product Code:	FXX

4. Device Description

The “SURGICAL MASK” is single use, blue color, without face shield, Flat Pleated type, utilizing elastic ear loops for wearing, and it has a Nose Piece design for fitting the facemask around the nose. The “SURGICAL MASK” is manufactured with three layers. The inner and outer layers are made of Non-woven fabric (Polypropylene), and the middle filter layer is made of a melt blown fabric (Polypropylene). The subject device is held in place over the user’s mouth and nose by two ear loops welded to the facemask. The elastic ear loop is made of Polyester and Spandex. The nose piece contained in masks is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of iron strip and polypropylene. The “SURGICAL MASK” is sold non-sterile and are intended to be single-use, disposable devices.

This product contains no components made with natural rubber latex.

5. Indication for use

The “SURGICAL MASK” is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The “SURGICAL MASK” is 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.

6. Technological Characteristics Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table

SE Comparisons	Proposed Devices	Predicate Device K200923	Similarities/ Differences
Name	Surgical Mask	Single-use Surgical Mask	/
Model	C015	FE2311	/
Classification	Class II	Class II	Same
Intended use	The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is 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.	The Single-use Surgical Mask (Model:FE2311) is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material.The Disposable Surgical Mask is 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
ASTM F2100 Level	Level 3	Level 3	Same
Mask Styles	Flat Pleated	Flat Pleated	Same
Design features	Ear loop	Ear loop	Same
Layers	3	3	Same
Color	Blue	Blue	Same
Target population	Adults	Adults	Same
Dimension (length)	175 ± 5 mm	175 ± 4 mm	Similar
Dimension (width)	95 ± 5 mm	95 ± 4 mm	Similar
Sterile	Non-sterile	Non-sterile	Same
Use	Single use, disposable	Single use, disposable	Same
Anatomical site	Nose and mouth	Nose and mouth	Same
Technology	Self-suction filter mask	Self-suction filter mask	Same
Environment of	OTC	OTC	Same

use			
Material of Outer layer	Non-woven fabric (Polypropylene)	Spun-bond polypropylene	Same
Material of middle layer	Melt blown fabric (Polypropylene)	Melt blown polypropylene filter	Same
Material of inner layer	Non-woven fabric (Polypropylene)	Spun-bond polypropylene	Same
Material of ear loops	Polyester and Spandex	Polyester	Similar
Material of Nose piece	Iron strip and Polypropylene	Metal Core Plastic	Same

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The proposed device SURGICAL MASK:

Performance:

1. **ASTM F2100-19** Standard Specification for Performance of Materials Used in Medical Face Masks was conducted on 3 discontinuous lots.

2. Bacterial Filtration Efficiency-Determine the bacterial filtration efficiency as directed in Test method **F2101**.

3. Differential Pressure -Determine breathing resistance or differential pressure as directed in **EN 14683:2019,Annex C**.

4. Sub-Micron Particulate Filtration-Determine particulate filtration efficiency as directed in Test Method **F2299**

5. Resistance to Penetration by Synthetic Blood-Determine synthetic blood penetration resistance as specified in Test Method **F1862.**

6. Flammability-Determine flammability as specified in **16 CFR Part 1610.**

Biocompatibility:

1. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro
2. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Standard	Test item	Test method	Criteria	Results
ASTM F2100-19	BFE	ASTM F2101-19	≥98%	32pass/ 32tested Accepted
	PFE	ASTM F2299-03(2017)	≥98%	32pass/ 32tested Accepted
	Differential Pressure	EN 14683 :2019+AC (2019)(E), Annex C	<6.0	32pass/ 32tested Accepted
	Synthetic Blood Penetration Resistance	ASTM F1862M-17	160mmHg	32pass/ 32tested Accepted
	Flammability	16 CFR Part 1610 (As Amendment In 2008)	(A) There are no burn times; or (B) There is only one burn time and it is equal to or greater than 3.5 seconds; or (C) The average burn time of two or more specimens is equal to or greater than 3.5 seconds.	Class 1
ISO 10993-5: 2009	In Vitro Cytotoxicity	In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article. The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37℃ ineubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37℃, 5% CO_2, >90% humidity for 24 hours. After the culture，the	The 50% extract of the test aticle should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated. The lower the Viab. % value, the higher the cytotoxic potential of the test article is. If viability is reduced to <70% of the blank, it has a cytotoxic potential. The Viab.% of the 100% extract of the test article is the final result.	Under the conditions of the test, the test article was found to be non-cytotoxic

		morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.		
ISO 10993-10: 2010	Skin Sensitization	we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010. The test article were extracted in Constant Temperature Vibrator at 50℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.	Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.	Under the conditions of the test, the test article was found to be non-sensitizing
	Skin Irritation test	we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010. The test article were extracted in Constant Temperature Vibrator at 50℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame	Use only (24±2) h, (48±2) h and (72±2) h observations for calculation. After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated	Under the conditions of the test, the test article was found to be non-irritating

		Oil.Apply 0.5 ml extracts of test article or control to 2.5 cm x 2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h.At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2)h following removal of the patches.	by dividing the sum of all the scores by 6 (two test/observation sites, three time points). To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals. When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.	

9. Conclusion

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