July 7, 2021

Changzhou Holymed Products Co., Ltd.
Shan Shang
Regulatory Correspondent
525 Changwu Road South
Changzhou, Jiangsu 213167
China

Re: K210524
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 15, 2021
Received: April 20, 2021

Dear Shan Shang:

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. PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210524

Device Name
Surgical Mask

Indications for Use *(Describe)*

The 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 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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510(k) Summary

Pursuant to 21 CFR 807.92

Prepared on April 14, 2021

1. Submitter

Manufacturer Name and Address:	Changzhou Holymed Products Co., Ltd. 525 Changwu Road South Wujin District, Changzhou Jiangsu, China 213167
Contact Person:	Ms. Shan Shang
Telephone Number:	+86 183 5120 0602
Email Address:	shan.shang@gogii.ca

2. Device Name

Device Name:	Surgical Mask
Common Name:	Surgical Mask
Regulatory Information:	
Classification Name:	Mask, Surgical
Regulation Number:	21 CFR 878.4040
Product Code:	FXX
Device Class:	Class II

3. Predicate

K160269 Level 3 Surgical Face Masks by San-M Package Co., Ltd. Particularly, the following model:

Model #	Style
EL30000	Ear-loop

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4. Device Description

The surgical mask is a three-layer flat-pleated mask made of nonwoven polypropylene materials. The inner layer (white color) and the outer layer (blue color) are made of spunbonded polypropylene to provide comfort and breathability; the middle filtration layer is made of melt-blown polypropylene. The three layers are bonded together sonically along the four edges with the inner layer slightly folded over the outer layer along the long edges.

The mask is fitted to cover the wearer's nose and mouth with ear-loops. The ear-loops are made of knitted polyester/ elastane. They are welded to the sides of the mask. The materials do not contain natural rubber latex.

A malleable polyethylene laminated aluminum nosepiece is placed between the layers along the top edge of the mask for extra comfort and fit around the wearer's nose.

The surgical mask is intended to be a single-use disposable device, provided non-sterile.

Product #	Style	Color
HM-02-01	Ear-loop	Blue

5. Intended Use/ Indication for Use

The 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 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.

6. Comparison to Predicate

(a) Technological Characteristics

Summarized in *Table 1* below is the comparison of the technological characteristics between the proposed and the predicate devices.

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Table 1 - Technological Characteristics Comparison			
Description	Proposed Device	Predicate Device	Comparison
510(k) Number	K210524	K160269 (EL30000)	N/A
Manufacturer	Changzhou Holymed Products Co., Ltd.	San-M Package Co., Ltd.	N/A
Common Name	Surgical Mask	Surgical Mask	Identical
Classification	Class II	Class II	Identical
Product Code	FXX	FXX	Identical
Intended Use	The 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 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.	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 materials. 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, provided non-sterile.	Identical
Material Composition			
Outer Cover	Polypropylene spunbonded	Polypropylene	Similar
Middle Layer	Polypropylene melt-blown	1. Polypropylene spunbond 2. Polypropylene meltblown	Similar
Inner Facing	Polypropylene spunbonded	Polypropylene	Similar
Nosepiece	Polyethylene laminated aluminum	Polyethylene coated steel wire	Similar
Ear-loop	Knitted polyester/ elastane	Polyester, polyurethane. Side tapes: Polyester spunbond (ear loops mask only)	Similar
Colorant	Polypropylene masterbatch	Unknown	Similar
Dimensions			
Length	95 ± 3mm	90 ± 3 mm	Similar
Width	175 ± 3mm	175 ± 5 mm	Similar

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Design Features	Ear-loop	Ear-loop	Identical
Color	Blue	White or blue	Similar
Mask Style	Flat-pleated	Flat-pleated	Identical
Sterility	Non-sterile	Non-sterile	Identical
Use Frequency	Single-use, disposable	Single use, disposable	Identical
ASTM 2100 Level	Level 3	Level 3	Identical

(b) Performance

(i) Clinical Test: Not applicable.

(ii) Non-Clinical Test:

The proposed device was tested and conformed to the following standards and the requirements stated in the *Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions posted on July 14, 2004.* All samples met the performance acceptance criteria and performed as effective as the predicate device.

Provided below in Table 2 is the summary of the non-clinical testing that was performed per specification of the standard and test methodology listed below. The results of the performance testing demonstrated the subject device met the acceptance criteria of the standard and the test methodology.

Table 2: Non-Clinical Performance Testing Table

Test Methodology	Purpose	Acceptance Criteria	Results
Fluid Resistance ASTM F1862	Determine the ability of the mask's material to resist penetration of blood and body fluids.	Pass/fail basis at any of three velocities corresponding to the range of human blood pressure Level 1 – 80 mmHg Level 2 – 120 mmHg Level 3 - 160 mmHg	Level 3 Passed at 160 mmHg. All 3 lots tested passed with no synthetic blood penetration observed at 160 mmHg, under the conditions of the test.

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Particulate Filtration Efficiency ASTM F2299	Determine the ability of the mask's material to prevent passage of aerosolized submicron particulates.	Pass/fail basis Level 1 – 95% Level 2 – 98% Level 3 – 98%	Level 3 Passed at > 99.9% Average Filtration Efficiency: AMSB-LOT202010007: >99.979% AMSB-LOT202011002: >99.9814% AMSB-LOT202011005: >99.984%
Bacterial Filtration Efficiency ASTM F2101-19	Determine the ability of the mask's material to prevent passage of aerosolized bacteria.	Pass/fail basis Level 1 – 95% Level 2 – 98% Level 3 – 98%	Level 3 Passed at ≥ 99.9% All samples tested passed with a filtration efficiency percentage of at least 99.9%, under the conditions of the test.
Differential Pressure (ΔP) ASTM F2100-19	Determine the resistance of the surgical facemask to air flowing through the mask.	Pass/fail basis Level 1 – <5 mm H_2O/cm^2 Level 2 – <6 mm H_2O/cm^2 Level 3 – <6 mm H_2O/cm^2	Level 1 Passed, < 5 mm H_2O/cm^2. AMSB-LOT202010007: ≤ 3.7 mm H2O/cm2. AMSB-LOT202011002: ≤ 3.7 mm H2O/cm2. AMSB-LOT202011005: ≤ 4.9 mm H2O/cm2.
Flammability 16 CFR Part 1610	Determine the ability of the mask to resist ignition to an externally applied ignition source.	Pass/fail basis Class 1, normal flammability specified in 16 CFR Part 1610.	Passed at Class 1 All samples tested achieved a Class 1 flammability rating under the conditions of the test.

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(c) Safety

To address the safety risks from wearing of the surgical mask, biocompatibility tests were performed according to the standard ISO 10993 as referenced in the *Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions posted on July 14, 2004*. All samples met the test criteria and are as safe as the predicate device. Test results are summarized in *Table 3* below.

Table 3: Summary of Biocompatibility Test Result and Comparison

Test Methodology	**Purpose**	**Acceptance Criteria**	**Results**
Cytotoxicity ISO 10993-5	Determine the biological response of mammalian cells in-vitro	Non-cytotoxic	Under the conditions of the study, non-cytotoxicity effect
Skin-irritation ISO 10993-10	Assess the potential of a medical device and its constituent materials to produce skin irritation	Non-irritating	Under the conditions of the study, non-irritation
Sensitization ISO 10993-10	Assess the potential of a medical device and its constituent materials to produce host sensitization	Non- sensitizing	Under the conditions of the study, non-sensitization

(d) Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission K210524, the Disposable Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.