November 16, 2022

KNH Surgical Face Mask
% Brian Wu
Specialist
KNH Enterprise Co., Ltd.
1, 2, 4F., No.66-1, Sanji,
Jiangjun Village, Jiangjun District,
725034 Tainan City,
Taiwan

Re: K203528
Trade/Device Name: KNH Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 21, 2022
Received: October 21, 2022

Dear Brian Wu:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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)*
K203528

Device Name
KNH Surgical Face Mask

Indications for Use *(Describe)*
The KNH Surgical Face Mask is intended to protect both patient and healthcare workers from the transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only.

Models: 1MMAB50DM2 (Level 1), 1MMAB50DM3 (Level 2)

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
K203528

1. **Type of Submission:** Traditional
   Date of Preparation: November 11th, 2022

2. **Submitter:** KNH Enterprise Co., Ltd.
   Address: 1, 2, 4F., No.66-1, Sanji, Jiangjun Village, Jiangjun District, 725034 Tainan City, Taiwan
   Phone: +886-2-2345-9909
   Fax: +886-2-2345-6299
   Contact: Brian WU
   Establishment Registration Number: 3016727877

3. **Identification of the Device:**
   Trade Name: KNH Surgical Face Mask
   Common Name: Surgical Masks
   Classification Name: Masks, Surgical
   Device Classification: II
   Regulation Number: 878.4040
   Classification Panel: General & Plastic Surgery
   Product Code: FXX

4. **Identification of the Predicate Device:**
   510(k) Number: K160269
   Predicate Name: Surgical Face Masks (Ear loops and Tie-on)
   Common Name: Surgical Mask
   Classification Name: Masks, Surgical Device
   Classification: II
   Regulation Number: 878.4040
   Classification Panel: General & Plastic Surgery Product
   Code: FXX

5. **Indications for Use:** The KNH Surgical Face Mask is intended to protect both patient and healthcare workers from the transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only. Models: 1MMAB50DM2 (Level 1), 1MMAB50DM3 (Level 2)

6. **Device Description:** The KNH Surgical Face Masks are four-layer surgical masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. This device is non-sterile and for single-use only. The mask is constructed of nonwoven fabric, including the outer cover web, insertion, filter web and the inner cover web, the mask is provided with ear loops and a nose wire for individualized fit. The models

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1MMAB50DM2 and 1MMAB50DN3 differ in the thickness of the filter web layer.

7. **Technical Comparison:**

	Subject device (K203528)	Predicate (K110455)	Comparison
Manufacturer	KNH Enterprise Co., Ltd.	San-M Package Co., Ltd.	-
Name	KNH Surgical Face Mask	Surgical Face Masks (Ear loops and Tie-on)	-
Common Name	Surgical Masks	Surgical Mask	Similar
Classification	II	II	Same
Product Code	FXX	FXX	Same
Indications For Use	The KNH Surgical Face Mask is intended to protect both patient and healthcare workers from the transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only. Models: 1MMAB50DM2 (Level 1), 1MMAB50DM3 (Level 2)	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, provided non-sterile. Level 1 Face Mask Models: # EL 1000, EL 10010, TO 10000, TO 10010 Level 2 Face Mask Models: # EL 20000, EL 20010, TO 20000, TO 20010 Level 3 Face Mask Models: # EL 30000, EL 30010, TO 30000, TO 30010	Similar
ASTM F2100 Level	1 and 2	1, 2, and 3	Similar to predicate level 1 and level 2 mask models
Tethers	Ear loop	Ear loop, Tie-on	
Number of Layers	4	4	Same
Outer Material	Polypropylene	Polypropylene	Similar
Inner Material	Polyethylene, Polypropylene	Polypropylene	Similar
Filter Material	1.Polypropylene Spunbond	1. Polypropylene spunbond	Similar

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	2.Polypropylene Meltblown	2. Polypropylene meltblown	
Tether Material	Ear-Loops: Polyamide elastic band Edge Wrap: Polypropylene Spunbond Nose-Wire: Polyethylene	Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond	Different
Color	Green	White or blue	Different
Dimensions	Length: 95± 5mm Width: 175± 5mm	Length: 90 ± 3 mm Width: 175 ± 5 mm Or Length: 90 ± 3 mm Width: 180 ± 5 mm	Similar
Mask Style	Pleated	Pleated with optional polyester visor	Similar
Fluid Resistance ASTM F1862	80 mmHg or 120 mmHg	80 mmHg, 120 mmHg, or 160 mmHg	Similar
Particulate Filtration Efficiency ASTM F2299	Pass at Avg. 99.49 % (Level 1) Pass at Avg. 99.31% (Level 2)	Pass at 99.6% (Level 1) Pass at 99.6% (Level 2) Pass at 99.7% (Level 3)	Similar
Bacterial Filtration Efficiency ASTM F2101	Greater than 99% (Level 1) Greater Than 99% (Level 2)	Pass at 98% Level 1 Pass at 98% Level 2 Pass at 99% Level 3	Similar
Differential Pressure Mil M36945 Appendix C	Pass at 2.5 to 2.9 mmH_2O/cm^2 (Level 1) Pass at 2.7 to 3.7 mmH_2O/cm^2 (Level 2)	Less than 2.0 mmH_2O/cm^2 Less than 1.6 mmH_2O/cm^2 or Less than 2.5 mmH_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility Skin Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
Biocompatibility Skin Irritation 10993-10	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
Biocompatibility Cytotoxicity 10993-5	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, non-cytotoxic	Same

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8. **Non-Clinical Testing:**

The proposed devices were tested and conformed to the following standards and requirements stipulated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission; including but not limited to ASTM F1862, ASTM F2101-19, Mil-M-36954C, 16 CFR 1610, ISO 10993-1, ISO 10993-5, ISO 10993-10.

Test	Purpose	Criteria	Result
Fluid Resistance ASTM F1862	To ensure adequate resistance to fluids	1MMAB50DM2 (Level 1): At least 29/32 pass at 80 mmHg for three non-consecutive lots	Pass
		1MMAB50DM3 (Level 2): At least 29/32 pass at 120 mmHg for three non-consecutive lots	Pass
Particulate Filtration Efficiency ASTM F2299	To demonstrate adequate resistance to particulate transmission	1MMAB50DM2 (Level 1): At least 29/32 pass at 95% or better efficiency for three non-consecutive lots	Pass
		1MMAB50DM3 (Level 2): At least 29/32 pass at 98% or better efficiency for three non-consecutive lots	Pass
Bacterial Filtration Efficiency ASTM F2101	To demonstrate adequate resistance to bacterial penetration	1MMAB50DM2 (Level 1): At least 29/32 pass at 95% or better efficiency for three non-consecutive lots	Pass
		1MMAB50DM3 (Level 2): At least 29/32 pass at 98% or better efficiency for three non-consecutive lots	Pass
Differential Pressure Mil M36945 Appendix C	To demonstrate adequate breathability	1MMAB50DM2 (Level 1): At least 29/32 pass at 5 mmH_2O/cm^2 or less for three non-consecutive lots	Pass
		1MMAB50DM3 (Level 2): At least 29/32 pass at 6 mmH2O/cm2 or less for three non-consecutive lots	Pass
Flammability 16 CFR 1610	To demonstrate adequate flammability resistance	At least 29/32 samples at class 1	Pass
Biocompatibility Skin Sensitization	To demonstrate low skin sensitization potential	Under the conditions of the test, not a sensitizer	Pass

ISO 10993-10			
Biocompatibility Skin Irritation 10993-10	To demonstrate low skin irritation potential	Under the conditions of the test, not an irritant	Pass
Biocompatibility Cytotoxicity 10993-5	To demonstrate low cytotoxicity	Under the conditions of the test, non-cytotoxic	Pass

9. **Clinical Testing:**
   No clinical testing was performed in support of this submission.

10. **Conclusion:** The conclusions drawn from the non-clinical testing demonstrate the KNH Surgical Face Masks are as safe, as effective and performs as well as or better than the level 1 and level 2 mask models of the predicate device K160269.