November 24, 2021

Nanjing 3H Medical Products Co., Ltd.
Chun Yang
Technology Department Manager
No.5 Zhushan Road Gaochun County Economic Development Zone
Nanjing, Jiangsu 211300
China

Re: K211295
Trade/Device Name: Surgical Mask (sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 21, 2021
Received: October 22, 2021

Dear Chun Yang:

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,

Yongqing Chen -S Date: 2021.11.24 14:38:23 -05'00'

For Clarence Murray III
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)*
K211295

Device Name
Surgical mask (sterile)

Indications for Use *(Describe)*
The Surgical Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**

**K211295**

## 1. Submitter Information

Company Name: Nanjing 3H Medical Products Co., Ltd. Establishment
Registration Number: K211295
Address: No.5 Zhushan Road Gaochun County Economic Development Zone
Nanjing Jiangsu, CHINA 211300
Phone: +86-25-57885555
Contact Person: Chun Yang (Technology Department manager)
E-mail: rdc@3hmedical.com
Date prepared: November 23, 2021

## 2. Subject Device Information

Type of 510(k) submission: Traditional
Common Name: Surgical Mask
Trade Name: Surgical mask (sterile)
Model: HKZ-01
Product Code: FXX
Regulation Number: 21 CFR 878.4040

## 3. Predicate Device Information

Submitter: B.J.ZH.F.Panther Medical Equipment Co., Ltd
Common Name: Surgical Face Mask
Trade Name: Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)
510(k) number: K202843
Product Code: FXX
Regulation Number: 21 CFR 878.4040

## 4. Device Description

Medical surgical mask is Sterile, single use, 3 layers, flat-pleated style with ear loops and nose clip. The outer layer and inner facing layer of face mask consist of Spunbond Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the users' mouth and face and includes a nose clip to provide a firm fit over the nose. The mask is a single use, disposable device, provided Sterile.

## 5. Indications for Use

The Surgical Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

## 6. Comparison of Technological Characteristics with the Predicate Device

**Table 1 - General Comparison**

| Elements of Comparison | Subject Device | Predicate Device | Comparison |
|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Product Name | | Surgical Mask (sterile) | Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile) | - |
| 510(k) Number | | K211295 | K202843 | - |
| **General Comparison** | | | | |
| Prescription/Over-the-counter use | | Over-the-counter use | Over-the-counter use | Same |
| | | The Surgical Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials. | The Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials. | Same |
| Type | | 3 Ply, Ear Loops, Flat-Pleated Style | 3 Ply, Ear Loops, Flat-Pleated Style | Same |
| Material | Outer facing layer | Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | Middle layer | Melt blown polypropylene filter | Melt blown polypropylene filter | Same |
| | Inner facing layer | Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | Nose clip | Polypropylene and galvanized iron wire | Polypropylene and galvanized iron wire | Same |
| | Ear loops | Nylon and spandex | Nylon and spandex | Same |
| Color | | Blue | Blue | Same |
| Dimension (Width) | | 9.5cm ± 0. 4cm | 9.5cm | Similar |
| Dimension (Length) | | 17.5cm ± 0. 4cm | 17.5cm | |
| Sterility | | Sterile | Sterile/Non-sterile | Different |
| Sterilization Method | | Ethylene Oxide ISO 11135 | Ethylene Oxide ISO 11135 | Same |
| Use | | Single Use, Disposable | Single Use, Disposable | Same |
| ASTM F2100 Level | | Level 2 | Level 2 | Same |

## 7. Summary of Non-Clinical Testing

Provided below is the nonclinical testing for the subject device. Three nonconsecutive lots were tested to demonstrate that the subject device met the standard and the test methodology.

| Test Method | Purpose | Acceptance Criteria | Result |
|---|---|---|---|
| Fluid Resistance ASTM F1862 | Verify the fluid resistance meets ASTM F2100 Level 2 | 32 Out of 32 pass at 120 mmHg | Pass |

| | | | |
|---|---|---|---|
| | requirements | | |
| Particulate Filtration Efficiency<br>ASTM F2299 | Verify the particulate filtration efficiency meets ASTM F2100 Level 2 requirements | ≥ 98% | Pass |
| Bacterial Filtration Efficiency<br>ASTM F2101 | Verify the bacterial filtration efficiency meets ASTM F2100 Level 2 requirements | ≥ 98% | Pass |
| Flammability Class16 CFR 1610 | Verify the flammability meets Class 1 requirements | Class 1 | Pass |
| Differential Pressure (Delta-P)<br>ASTM F2100-19 | Verify the differential pressure meets ASTM F2100 Level 2 requirements | < 6.0 $mmH_20/cm^2$ | Pass |
| ASTM F2100<br>Level 2 ASTM F2100 | Verify all ASTM F2100 Level 2 requirements are met | Meets requirements at Level 2 | Pass |
| Biocompatibility Skin Irritation ISO 10993-10 | Verify the device is non-irritating under ISO 10993-10 testing | Under the conditions of the study, non-irritating | Pass |
| Biocompatibility Skin Sensitization ISO 10993-10 | Verify the device is not a sensitizer under ISO 10993-10 testing | Under the conditions of the study, non-sensitizing | Pass |
| Biocompatibility Cytotoxicity ISO-10993-5 | Verify the device is not cytotoxic under ISO 10993-5 testing | Under the conditions of the study, non-cytotoxic | Pass |
| EO/ECH Residues<br>ISO 10993-7 | Verify low levels of sterilant residuals | EO ≤ 4mg/device<br>ECH ≤ 9mg/device | Pass |

## 8. Clinical Testing

No clinical testing was included in this submission.

## 9. Conclusion

The conclusions from the nonclinical testing demonstrate that the HKZ-01 Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Surgical Face Mask (K202843).