September 1, 2022

Hantech Medical Device Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K221038
Trade/Device Name: Disposable Medical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 25, 2022
Received: August 29, 2022

Dear Mr. Yungvirt:

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)*
K221038

Device Name
Disposable Medical Masks

Indications for Use *(Describe)*
The Disposable Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. They are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.

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. SUBMITTER

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Summary Preparation Date: 2021.12.6

III. DEVICE

Name of Device	Disposable Medical Masks
Models	Neo101, Neo102
Common Name	SURGICAL MASK
Classification Name	Mask, Surgical
Classification	Class II
Regulation Number	21 CFR 878.4040
Regulation Number	FXX
Review Panel:	General Hospital

IV. PREDICATE DEVICE

Predicate Device 510k number: K211899
Predicate Device Manufacturer: Hubei YI-YA PROTECTIVE PRODUCTS CO., LTD

V. Device Description

V1. Indications for use of the device:
The Disposable Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. They are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.

V2. Device Description:
The Disposable Medical Masks are single use, three-layer, flat-folded masks with ear loops and nose clamp. The Disposable Medical Masks are manufactured with three layers, the inner and outer layers are made of non-woven fabric, and the middle layer is made of melt blown Fabric. The ear loops are held in place over the users' mouth and nose by two ear loops welded to the face mask. The ear loops are made of Polyamide & Spandex. The nose clamp in the layers of face mask is to allow the user to fit the face mask around their nose, which is made of galvanized iron wire wrapped with PE material. The Disposable Medical Masks will be provided in white, blue, and purple which are sold non- sterile and are intended to be single use, disposable devices.

VI. Predicate Comparison

Table 6.1 Surgical Face Mask Predicate Comparison

Models	**Subject Device**	**Predicate Device K211899**	**Comparison**
Product name	Disposable Medical Masks, Neo101, Neo102	SURGICAL FACE MASK, Ear loops	Similar
Product code	FXX	FXX	Same
Regulation number	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indications for use	The Disposable Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. They are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.	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. They 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
Design Features	Ear Loops, Flat-pleated, 3 layers	Ear Loops, Flat-pleated, 3 layers	Same
Materials			
Outer layer	Non-woven fabric (polypropylene)	Spunbond Polypropylene	Differences resolved by biocompatibility

			testing
Inner layer	White non-woven fabric (polyethylene, polyester)	Spunbond Polypropylene	Differences resolved by biocompatibility testing
Filter layer	Melt-blown Polypropylene	Melt-blown Polypropylene	Same
Nose clip (Nose clamp)	Galvanized iron wire wrapped with PE material	iron bar coated with polyolefin	Differences resolved by biocompatibility testing
Ear loops	Polyamide & Spandex	Spandex	Differences resolved by biocompatibility testing
Other Design Features			
Color	White, Blue, Purple	White	Differences resolved by biocompatibility testing
Dimension (Length* Width)	17.5 x 9.5cm	(16.0cm±0.5cm) x (11.0cm±0.5cm)	Differences resolved by performance testing
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Single Use	Yes	Yes	Same
Sterile	No	No	Same
ASTM F2100 Level	Level 3	Level 2	Subject device demonstrates ed higher resistance to fluid penetration
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10	Comply with ISO 10993-5, ISO 10993-10	Same

VII. Summary of Non-Clinical Test

Non-clinical tests were conducted using 3 nonconsecutive lots with 32 samples for each model of surgical mask to verify that the proposed device met all design specifications as was same to the predicate device.

The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions (Document issued on: March 5, 2004 and a

correction posted on July 14, 2004)

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at A Known Velocity);
- EN 14683, Medical Face Masks - Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

Test Methodology	**Purpose**	**Acceptance Criteria: ASTM F2100 Level 3**	**Result**
Fluid Resistance, Synthetic Blood Penetration ASTM F1862	The purpose of the test is to evaluate the Resistance to penetration by synthetic blood, Minimum pressure in mmHg	≧29 samples out of 32 pass (AQL 4%) at 160 mmHg for level 3	PASS 32 out of 32 passes at 160 mmHg for level 3
Particulate Filtration Efficiency ASTM F2299	The purpose of the test is to evaluate the Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	≥ 98% 29 out of 32 pass	PASS
Bacterial Filtration Efficiency ASTM F2101	The purpose of the test is to evaluate the Bacterial filtration efficiency (BFE) (%)	≥ 98% 29 out of 32 pass	PASS
Differential Pressure (Delta P) EN 14683 Annex C	The purpose of the test is to evaluate the Different pressure (Delta-P)	< 6.0mmH_2O/cm^2 29 out of 32 pass	PASS
Flammability, 16 CFR 1610	The purpose of the test is to evaluate the Flame spread	Class 1	PASS
Cytotoxicity, ISO 10993-5	The purpose of the testing is to demonstrate the biocompatibility safety of	Non-cytotoxic	PASS

	the subject device.		
Irritation, ISO 10993-10	The purpose of the testing is to demonstrate the biocompatibility safety of the subject device.	Non-irritating	PASS
Sensitization, ISO 10993-10	The purpose of the testing is to demonstrate the biocompatibility safety of the subject device.	Non-sensitizing	PASS

VIII. Summary of Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject devices are substantially equivalent to the predicate devices with respect to the indications for use, target populations, treatment method, and technological characteristics.