March 25, 2022

KDI Med Supply
% Prithul Bom
Accredited Person, Reviewer
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220637
Trade/Device Name: 3 Ply Medical Grade Single Use Procedural Disposable Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 3, 2022
Received: March 4, 2022

Dear Prithul Bom:

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)*
K220637

Device Name
3 Ply Medical Grade Single Use Procedural Disposable Face Mask

Indications for Use *(Describe)*
The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare provider 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 bodily 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 – K220637

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

Type of Submission: Traditional

Date Prepared: 3/24/2022

Device Type: Surgical Mask

I. SUBMITTER

KDI Med Supply
206 Lynn St. Fremont, OH 43420 USA
Phone: (567) 280-9936 or (419) 307-0305
Fax: N/A

Contact Person: Yolanda Davis
Email: kevin@kdimedsupply.com

II. SUBJECT DEVICE

Device/Trade Name:	3 Ply Medical Grade Single Use Procedural Disposable Face Mask
Classification Name:	Mask, Surgical
Regulation:	21 CFR 878.4040
Regulatory Class:	Class II
Common Name:	Level 2 Medical Grade Mask
Device Panel:	General Hospital
Product Code:	FXX

III. PREDICATE DEVICE

Manufacturer: Qiqihar Hengxin Medical Supplies, Ltd.
Trade/Device Name: Single-Use Surgical Mask with Ear Loop (K201691)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The KDI Med Supply surgical face mask is with blue outer color layer and white inner and middle layer. Subject device is a flat pleated type mask, utilizing ear loop way for wearing, and it has a nose piece designed for fitting the face mask around the nose. The mask materials consist of an outer layer (polypropylene spunbond), inner layer (polypropylene spunbond), filter (polypropylene melt-blown) and ear-loops. The masks contains a malleable nose piece to provide a firm fit over the nose and to secure the mask over the users mouth and face. The mask has level II fluid resistance under ASTM F2100. The mask is a single use, provided non-sterile. This product contains no components made with natural rubber latex.

V. INDICATIONS FOR USE

The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare provider 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 bodily fluids. This is a single use, disposable device provided non-sterile.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in Table 1 below

Table 1 – Comparison of Technological Characteristics

Feature	**Subject Device: 3 Ply Medical Grade Single Use Procedural Disposable Face Mask (K220637)**	**Predicate Device: Single-Use Surgical Face Mask with Ear Loop (K201691)**	**Result**
Indications for Use	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare provider 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 bodily fluids. This is a	The single-use surgical mask with ear loop is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single Use Surgical Mask with ear loop is intended for use in infection control practices to reduce the potential	Same

	single use, disposable device provided non-sterile.	exposure to blood and bodily fluids. This is a single-use, disposable device(s), provided non-sterile.	
Materials			
Inner Facing Layer	Spun-Bond Polypropylene	Spun-Bond Polypropylene	SAME
Middle Layer	Melt Blown polypropylene	Melt Blown polypropylene	SAME
Outer Facing Layer	Spun-bond polypropylene	Spun-Bond Polypropylene	SAME
Nose Piece	Wire, malleable nosepiece, plastic-coated steel	Wire, malleable aluminum nosepiece	Different
Ear Loop	Polyester and spandex materials	polyester	SAME
Color	Blue Outer Layer	Blue Outer Layer	SAME
Mask Style	Flat pleated, ear loop	Flat pleated, ear loop	SAME
Dimension (Width) Adult	9.5 cm +/-0.5cm	9 cm +/-1cm	SIMILAR
Dimension (Length) Adult	17 cm +/-0.5cm	18 cm +/-1 cm	SIMILAR
Single Use	Yes	Yes	SAME
OTC Use	Yes	Yes	SAME
Sterility	Non-Sterile	Non-Sterile	SAME

VII. PERFORMANCE DATA

Table 2 – Benchtop Performance Testing

Item	**Subject Device: 3 Ply Medical Grade Single Use Procedural Disposable Face Mask (K220637)**	**Predicate Device: Single-Use Surgical Face Mask with Ear Loop (K201691)**	**Result**
ASTM F2100 Level	II	II	PASS
Fluid resistance (ASTM F1862)	32 out of 32 pass at 120 mmHG (16.0 kPa)	31 out of 32 pass at 120 mmHg (16.0 kPa)	PASS
Particulate Filtration (ASTM F2299)	>99.99%	> 99%	PASS
Bacterial Filtration (ASTM F2101)	>99.9%	> 99%	PASS

Differential Pressure (Delta-P) (ASTM F2100)	8 Liters per minute (L/min) < 6.0 mmH20/cm2	< 5.0 mmH20/cm2	PASS
Biocompatibility IS0 10993	Irritation (ISO 10993-10), Sensitization (ISO 10993-10), Cytotoxicity (ISO 10993-5)	Irritation (ISO 10993-10), Sensitization (ISO 10993-10), Cytotoxicity (ISO 10993-5)	PASS
Flammability	Class 1	Class 1	PASS

Summary of Non-Clinical Performance Testing

Table 3: The following standards have been used to evaluate the KDI Med Supply's 3 Ply Medical Grade Single Use Procedural Disposable Face Mask

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)
ASTM F2299	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2101	Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
EN 14683	2019 Standard Test Method for Differential Pressure 16 CFR Part 1610 Standard for Flammability
ISO 10993-1	1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
ISO-10993-10	10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Table 4: The following performance data has been provided from 3 nonconsecutive lots to demonstrate that the subject device meets the criteria of the standards.

Test Methodology, Standard	Purpose	Acceptance Criteria	Results
ASTM F1862	Resistance to Penetration by synthetic blood	120 mm Hg	120 mm Hg
ASTM F2299	Particulate filtration efficiency	>98%	> 99.99%
ASTM F2101	Bacterial Filtration	>98%	>99.99%
16 CFR 1610	Flammability	Class 1	Class 1

ASTM F2100	Differential Pressure (Delta-P)	< 6.0 mm H20/cm2	< 6.0 mm H20/cm2

VIII. CONCLUSION

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, and effective, and performs well as or better than the legally marketed predicate device.