April 23, 2021

String King Lacrosse, LLC
% Thomas Frasca
President
19100 S Vermont Ave.
Gardena, CA, 90248 USA

Re: K202607
Trade/Device Name: Surgical Mask - Level 3 & Procedure Mask - Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 9, 2020
Received: September 9, 2020

Dear Thomas Frasca:

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,

For Ryan Ortega, Ph.D.
Acting 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)*
K202607

Device Name
Surgical Mask – Level 3 & Procedure Mask – Level 3

Indications for Use *(Describe)*
The disposable 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.

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 – K202607

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

I. SUBMITTER

String King Lacrosse, LLC
19100 S Vermont Ave.
Gardena, CA, 90248 USA
Tel: +1.508.654.1988
Fax: N/A

Contact Person: Thomas Frasca
Date Prepared: April 22, 2021

II. DEVICE

Name of Device:	Surgical Mask – Level 3 & Procedure Mask – Level 3
Classification Name:	Surgical Mask
Regulation:	21 CFR § 878.4040
Regulatory Class:	Class II
Product Classification Code:	FXX

III. PREDICATE DEVICE

Predicate Manufacturer:	DemeTECH Corporation
Predicate Trade Name:	DemeMASK
Predicate 510(k):	K201479

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The 3-ply surgical mask is non-sterile, disposable, single-use surgical mask. It is manufactured with three layers, the inner and outer layers are made of non-woven, spun-bond polypropylene, while the middle filter layer is made of a non-woven, melt-blown polypropylene.

V. INDICATIONS FOR USE

The disposable 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence in Table 1 below.

Table 1 – Comparison of Technological Characteristics

Device	Proposed Device - Surgical Mask – Level 3 & Procedure Mask – Level 3 (K202607)	Predicate Device - DemeMASK (K201479)	Result
Manufacturer	StringKing	DemeTECH Corporation	N/A
510K Number	K202607	K201479	N/A
Product Common Name	SURGICAL FACE MASK	SURGICAL FACE MASK	Identical
Product Code	FXX	FXX	Identical
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Identical
Intended Use	The disposable 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.	The Disposable 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.	Identical
Model	3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops or Tie-On	No tie-on option for subject device
Materials			
Outer Facing Layer	Spun-Bond Polypropylene (same material as inner layer)	Spunbond Polypropylene	Same
Middle Layer	Melt-blown Polypropylene	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Spun-Bond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	LDPE cover and galvanized wire core	Single Galvanize Wire, Coated By PE	Same
Ear Loops	Nylon, Spandex, Polyester	not made with natural rubber latex	Same

Color	Blue	White	Different, performance supported by biocompatibility and performance test data
Dimension (Width)	9.5 cm ± 0.5 cm	9.5 cm ± 1.0 cm	Similar
Dimension (Length)	17.5 cm ± 1 cm	17.5 cm ± 1.0 cm	Same
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 3	Level 3	Same, see Table 2
Biocompatibility ISO 10993-5 and ISO 10993-10	Non-cytotoxic, nonsensitizing, and nonirritating	Non-cytotoxic, nonsensitizing, and nonirritating	Same, see Table 3

VII. NON-CLINICAL DATA

The subject 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)] Submission issued on March 5, 2004. A summary of the benchtop performance testing results is provided below in Table 2 along with the acceptance criteria and the predicate device's reported results.

Table 2 – Benchtop Performance Testing

Item	Proposed Device - Surgical Mask – Level 3 & Procedure Mask – Level 3	Predicate Device - DemeMASK (K201479)	Acceptance Criteria	Subject Device Result
Level 3 Fluid Resistance Performance ASTM F1862	32 Out of 32 pass at 160 mmHg	32 Out of 32 pass at 160 mm Hg	29 Out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	99.67-99.80%	≥99%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	99.6 – 99.9%	≥99%	≥ 98%	Pass
Differential Pressure ASTM F2100	4.8-5.0 mmH_20/cm^2	Avg. 3.6 mmH_20/cm^2	< 6.0 mmH_20/cm^2	Pass
Class 1 Flammability 16 CFR 1610	Did not ignite or Ignited but Extinguished	Class 1	< 3.5 second burn time	Pass

Sterilization & Shelf-life Testing

Not Applicable (This is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.)

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

Table 3 - Biocompatibility Testing

Standards	Proposed Device - Surgical Mask – Level 3 & Procedure Mask – Level 3	Predicate Device - DemeMASK (K201479)	Result
Cytotoxicity – ISO 10993-5	Under the conditions of the study the device is non-cytotoxic	Under the conditions of the study the device is non-cytotoxic	Pass
Skin Sensitization – ISO 10993-10	Under the conditions of the study the device is non-sensitizing	Under the conditions of the study the device is non-sensitizing	Pass
Skin Irritation – ISO 10993-10	Under the conditions of the study the device is non-irritating	Under the conditions of the study the device is non-irritating	Pass

Software Verification and Validation Testing
Not Applicable (Passive Device)

Electrical safety and electromagnetic compatibility (EMC)
Not Applicable (Passive Device)

Human Clinical Performance Testing
Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS
The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well or better than the legally marketed predicate device (K201479), manufactured by DemeTECH Corporation.