May 19, 2022

SafeSource Direct, LLC
% Prithul Bom
Most Repsonsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K221134
Trade/Device Name: Procedure Mask with Ear Loops and Surgical Mask with Ties
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 18, 2022
Received: April 19, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221134

Device Name
Procedure Mask with Ear Loops and Surgical Mask with Ties

Indications for Use *(Describe)*
The SafeSource Direct Procedure Mask with Ear Loops is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, bodily fluids, and particulate material. These procedure masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluid. The procedure masks are single use, disposable devices, provided non-sterile.

The SafeSource Direct Surgical Mask with Ties is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, bodily fluids, and particulate material. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluid. The surgical masks are single use, disposable devices, 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.

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510(k) Summary

Version: 2 Revision Date: 4/12/2022

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information

Company:	Robbie Wicks Vice President / COO SafeSource Direct, LLC 200 St Nazaire Rd. Broussard, LA 70518 United States Telephone: 337-210-7943 Fax: 337-202-8099 rwicks@safesourcedirect.com
Contact:	Robbie Wicks Vice President / COO SafeSource Direct, LLC 200 St Nazaire Rd. Broussard, LA 70518 United States Telephone: 337-210-7943 Fax: 337-202-8099 rwicks@safesourcedirect.com
Date Summary Prepared:	April 12, 2022

Name of the Device

Trade Name:	Procedure Mask with Ear Loops and Surgical Mask with Ties
Common Name:	Mask, surgical
Classification Name:	Surgical apparel
Review Panel:	General & Plastic Surgery (SU)
Regulation:	878.4040
Class:	Class II
Product Code:	FXX

Equivalence Claimed to Predicate Device

The Procedure Mask with Ear Loops and Surgical Mask with Ties is equivalent to the Procedure Mask, Surgical Mask (K202899), manufactured by Kenpax International Limited.

Trade Name:	Procedure Mask / Surgical Mask
Common Name:	Surgical Mask
Classification Name:	Surgical Face Mask
Product Code:	FXX

Device Description

The Procedure Mask with Ear Loops (PM3001, PM3003) is a non-sterile, single use, three-layer, flat-folded mask with ear loops, and a nose wire. The Procedure Mask with Ear Loops is constructed of inner and outer layers consisting of spunbond polypropylene and a middle layer of meltblown polypropylene. The welded ear loops made of spandex/elastane fiber and polyester filament keep the mask close to the user's mouth and nose. The ethylene propylene copolymer coated aluminum nose wire allows the user to fit the mask around their nose.

The Surgical Mask with Ties (SM3001, SM3003) is a non-sterile, single use, three-layer, flat-folded mask with ties, and a nose wire. The Surgical Mask with Ties is constructed of inner and outer layers consisting of spunbond polypropylene and a middle layer of meltblown polypropylene. The welded polypropylene tie straps keep the mask close to the user's mouth and nose. The ethylene propylene copolymer coated aluminum nose wire allows the user to fit the mask around their nose.

Substantial Equivalence Comparison

Substantial Equivalence Table		
Characteristic	**Proposed Device: Procedure Mask with Ear Loops and Surgical Mask with Ties**	**Primary Predicate Device: Procedure Mask, Surgical Mask (K202899)**
Intended Use	To protect both patients and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.	To protect both patients and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.
Indication for Use	The SafeSource Direct Procedure Mask with Ear Loops is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, bodily fluids, and particulate material. These procedure masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluid. The procedure masks are single use, disposable devices, provided non-sterile. The SafeSource Direct Surgical Mask with Ties is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, bodily fluids, and particulate material. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluid. The surgical masks are single use, disposable devices, provided non-	The Procedure Masks/ Surgical 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(s), provided non-sterile.

	sterile.	
510(k) No.	Pending	K202899
Manufacturer	SafeSource Direct, LLC	Kenpax International Limited
Classification	Class II, FXX (21 CFR 878.4040)	Class II, FXX (21 CFR 878.4040)
Model Description	PM3001: Procedure Mask with Ear Loops, ASTM Level 1 PM3003: Procedure Mask with Ear Loops, ASTM Level 3 SM3001: Surgical Mask with Ties, ASTM Level 1 SM3003: Surgical Mask with Ties, ASTM Level 3	68-8506-G: Procedure Mask, Earloop, ASTM Level 1 65-8508-G: Procedure Mask, Earloop, ASTM Level 3 68-8536-B: Surgical Mask, Tie-on, ASTM Level 1 68-8538-B: Surgical Mask, Tie-on, ASTM Level 3
Design Features	Ear Loops, Tie-on	Ear Loops, Tie-on
Mask Style	Flat Pleated	Flat Pleated
Outer Facing Layer	Blue spunbond (polypropylene) Level 1: 25 gsm Level 3: 25 gsm	Spunbond polypropylene Level 1: 22 gsm Level 3: 25 gsm
Middle Layer	White meltblown (polypropylene) Level 1: 25 gsm Level 3: 25 gsm	Melt-blown polypropylene Level 1: 22 gsm Level 3: 25 gsm
Inner Facing Layer	Blue spunbond (polypropylene) Level 1: 25 gsm Level 3: 25 gsm	Spunbond polypropylene Level 1: 22 gsm Level 3: 25 gsm
Nose Piece	Dual aluminum wire, white ethylene propylene copolymer	Polyethylene coated steel wire
Ear Loops	White knitted spandex/elastane fiber, polyester filament	Nylon, spandex
Tie-On	White spunbond (polypropylene)	Spunbond polypropylene
Color	Blue, White	Blue, Green
Dimension (Width)	3.74” ± 0.40”	95 ± 5 mm
Dimension (Length)	6.89” ± 0.40”	178 ± 5 mm
OTC Use	Yes	Yes
Sterility	Non-sterile	Non-sterile
Use	Single Use, Disposable	Single Use, Disposable
ASTM F2100 Level	Level 1, Level 3	Level 1, Level 3
Fluid Resistance	Meet ASTM F1862/F1862M-17	Meet ASTM F1862-17
Particulate Filtration Efficiency (PFE)	Meet ASTM F2299/F2299M-03 (2017)	Meet ASTM F2299-17

Bacterial Filtration Efficiency (BFE)	Meet ASTM F2101-19	Meet ASTM F2101-19
Differential Pressure	Meet EN 14683:2019+AC:2019 Annex C	Meet EN 14683:2019, Annex C
Flammability	Meet 16 CFR 1610 (Oct 2008)	Meet 16 CFR 1610
Cytotoxicity	Non-cytotoxic	Non-cytotoxic
Irritation	Negligibly irritating (Primary Irritation Index 0.0)	Non-irritating
Sensitization	Not a contact sensitizer	Non-sensitizing

Additional Information

Summary of Non-Clinical Testing Conducted

Non-clinical testing was conducted to verify the proposed device meets the same design specifications as the predicate device. Test results demonstrated the proposed device complies with the requirements of US FDA *Guidance for Industry and FDA Staff / Surgical Masks - Premarket Notification [510(k)] Submissions* posted on July 14, 2004 and the following standards:

- ASTM F2100-19, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F2101-19, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus aureus
- EN 14683:2019 + AC:2019 Annex C, Medical Face Masks—Requirements and Test Methods
- ASTM F2299/F2299M-03(2017), Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F1862/F1862M-17, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles
- ISO 10993-5: 2009, Biological Evaluation of Medical Devices -- Part 5: Tests For *In Vitro* Cytotoxicity, and
- ISO 10993-10: 2010, Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Tables 1 and 2 summarize the performance test data.

Table 1 Comparison of Performance Testing for Proposed ASTM Level 1 Procedure Mask with Ear Loops (PM3001) and Surgical Mask with Ties (SM3001) with Predicate Device

Non-Clinical Test	Acceptance Criteria (ASTM Level 1)	Proposed Device	Predicate Device (K202899)	Proposed Device	Predicate Device (K202899)
		PM3001	68-8506-G	SM3001	68-8536-B

Fluid Resistance	≥ 29 of 32 pass at 80 mmHg	Pass (96/96) at 80 mmHg, 32 samples from 3 non-consecutive lots	32 of 32 passed at 80 mmHg, 3 lots	Pass (96/96) at 80 mmHg, 32 samples from 3 non-consecutive lots	32 of 32 passed at 80 mmHg, 3 lots
Particulate Filtration Efficiency	≥ 95% at 0.1 micron	Pass (96/96) at > 95%, 32 samples from 3 non-consecutive lots	97.4%, 97.5%, 97.5%	Pass (96/96) at > 95%, 32 samples from 3 non-consecutive lots	97.2%, 97.1%, 97.1%
Bacterial Filtration Efficiency	≥ 95%	Pass (96/96) at > 95%, 32 samples from 3 non-consecutive lots	99.9%, 3 lots	Pass (96/96) at > 95%, 32 samples from 3 non-consecutive lots	99.9%, 3 lots
Differential Pressure	< 5.0 mmH2O/cm2	Pass (96/96) at < 5.0 mmH_2O/cm^2, 32 samples from 3 non-consecutive lots	2.9, 2.8, 2.7 mmH_20/cm^2	Pass (95/96) at < 5.0 mmH_2O/cm^2, 32 samples from 3 non-consecutive lots	3.7, 3.4, 3.7 mmH_20/cm^2
Flammability	Class 1	Pass (96/96) at Class 1, 32 samples from 3 non-consecutive lots	Class 1	Pass (96/96) at Class 1, 32 samples from 3 non-consecutive lots	Class 1
Cytotoxicity		Non-cytotoxic	Non-cytotoxic	Non-cytotoxic	Non-cytotoxic
Irritation		Negligibly irritating (Primary Irritation Index 0.0)	Non-irritating	Negligibly irritating (Primary Irritation Index 0.0)	Non-irritating
Sensitization		Not a contact sensitizer	Non-sensitizing	Not a contact sensitizer	Non-sensitizing

Table 2 Comparison of Performance Testing for Proposed ASTM Level 3 Procedure Mask with Ear Loops (PM3003) and Surgical Mask with Ties (SM3003) with Predicate Device

Non-Clinical Test	Acceptance Criteria (ASTM Level 3)	Proposed Device	Predicate Device (K202899)	Proposed Device	Predicate Device (K202899)
		PM3003	68-8508-G	SM3003	68-85368-B

Fluid Resistance	≥ 29 of 32 pass at 160 mmHg	Pass (96/96) at 160 mmHg, 32 samples from 3 non-consecutive lots	32 of 32 passed at 160 mmHg, 3 lots	Pass (96/96) at 80 mmHg, 32 samples from 3 non-consecutive lots	32 of 32 passed at 160 mmHg, 3 lots
Particulate Filtration Efficiency	≥ 98% at 0.1 micron	Pass (95/96) at > 98%, 32 samples from 3 non-consecutive lots	98.2%, 98.4%, 98.4%	Pass (95/96) at > 98%, 32 samples from 3 non-consecutive lots	98.4%, 98.4%, 98.3%
Bacterial Filtration Efficiency	≥ 98%	Pass (96/96) at > 98%, 32 samples from 3 non-consecutive lots	99.9%, 3 lots	Pass (96/96) at > 98%, 32 samples from 3 non-consecutive lots	99.9%, 3 lots
Differential Pressure	< 6.0 mmH2O/cm2	Pass (96/96) at < 6.0 mmH_2O/cm^2, 32 samples from 3 non-consecutive lots	3.4, 3.0, 3.0 mmH_20/cm^2	Pass (96/96) at < 6.0 mmH_2O/cm^2, 32 samples from 3 non-consecutive lots	4.1, 3.4, 3.4 mmH_20/cm^2
Flammability	Class 1	Pass (96/96) at Class 1, 32 samples from 3 non-consecutive lots	Class 1	Pass (96/96) at Class 1, 32 samples from 3 non-consecutive lots	Class 1
Cytotoxicity		Non-cytotoxic	Non-cytotoxic	Non-cytotoxic	Non-cytotoxic
Irritation		Negligibly irritating (Primary Irritation Index 0.0)	Non-irritating	Negligibly irritating (Primary Irritation Index 0.0)	Non-irritating
Sensitization		Not a contact sensitizer	Non-sensitizing	Not a contact sensitizer	Non-sensitizing

Summary of Clinical Testing Conducted

No clinical testing is included in this submission.

Substantial Equivalence Conclusion

Based on comparison of the subject device to the predicate device and the non-clinical tests performed, it can be concluded that the proposed Procedure Mask with Ear Loops and Surgical Mask with Ties are as safe and effective, and perform as well as the legally marketed predicate device Kenpax International Limited Procedure Mask/Surgical Mask cleared under premarket notification K202899.