June 24, 2022

Little Rapids Corporation
Tom Diedrich
Manager of Product Development and Quality
2273 Larsen Road
Green Bay, Wisconsin 54303

Re: K220377
Trade/Device Name: Procedure Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 25, 2022
Received: May 31, 2022

Dear Tom Diedrich:

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.

K220377

Device Name
Procedure Mask

Indications for Use *(Describe)*
The Procedure 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. All models 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.

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510(k) Summary

Date Prepared: June 17, 2022

A. Applicant:

LITTLE RAPIDS CORPORATION
Address: 2273 Larsen Road
Green Bay, WI 54303

Submission Correspondent(s):

Primary contact: Tom Diedrich
Address: 2273 Larsen Road
P.O. Box 19031
Green Bay, WI 54307-9031
Office Phone: (920) 490-5302
Email: tdiedrich@littlerapids.com

Secondary contact: David Ledvina
Address: 2273 Larsen Road
P.O. Box 19031
Green Bay, WI 54307-9031
Office Phone: (920) 490-5315
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B. Device:

Device Name: Procedure Mask

Intended Branding: Graham Medical

Models: GFM31A (including MR Safe version), GFM42A, GFM43A

Regulatory Information:

Classification Name: Mask, Surgical

Regulation Description: Surgical Apparel

Regulation Specialty: General & Plastic Surgery

Review Panel: General Hospital

Product code: FXX

Classification: Class II

Regulation Number: 21 CFR 878.4040

C. Device Description:

- Model GFM31A Procedure Mask will be provided with a nose wire for general medical use, and without a nose wire for use in an MRI environment. This model of Procedure Mask is manufactured with three layers. The user facing layer is made of white polypropylene spunbond; the filtration/middle layer is made of white polypropylene meltblown; and the outer layer is made of blue polypropylene spunbond. The ear loops are welded to the mask and are used to keep the mask close to the mouth and the nose. This device is not made with natural rubber latex. The PVC coated nose wire, when present, is used to fit the facemask around the user's nose. The product intended to be used in an MRI environment is constructed with the same materials except for the nose wire. The Procedure Mask is to be provided as a non-sterile, single use, disposable device.

- Model GFM42A Procedure Mask is manufactured with four layers. The user facing layer is made of white polypropylene spunbond; the filtration layer is made of white polypropylene meltblown; the next layer is made of blue polypropylene spunbond; and the outer layer is made of blue polypropylene spunbond. The ear loops are welded to the mask and are used to keep the mask close to the mouth and the nose. This device is not made with natural rubber latex. The PVC coated nose wire is used to fit the facemask around the user's nose. The Procedure Mask is to be provided as a non-sterile, single use, disposable device.

- Model GFM43A Procedure Mask is manufactured with four layers. The user facing layer is made of white polypropylene spunbond; the filtration layer is made of white polypropylene meltblown; the next layer is made of blue polypropylene spunbond; and the outer layer is made of blue polypropylene spunbond. The ear loops are welded to the mask and are used to keep the mask close to the mouth and the nose. This device is not made with natural rubber latex. The PVC coated nose wire is used to fit the facemask around the user's nose. The Procedure Mask is to be provided as a non-sterile, single use, disposable device.

D. Indications for use of the device:

The Procedure 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. All models are single use, disposable devices, provided non-sterile.

E. Shelf Life

A shelf-life is not applicable to this product because of low likelihood of time-dependent degradation.

F. Labeling – Instructions for Use

Procedure Masks have commonly known directions for use and fall under the exemption for Instructions for Use under 21CFR Chapter 1 Subchapter H part 801 Subpart D Sec 801.116.

G. Predicate Devices:

- **Model GFM31A – ASTM Level 1**

Primary Predicate

510K Number: K111402
Kimberly Clark Corporation
Device Name: Surgical Mask
Model: KC200 (ASTM Level 2)

Additional Predicate

510K Number: K202137
U-Play Products Corporation
Device Name: Disposable Medical Mask
Model: Y01 (ASTM Level 1)

- **Model GFM42A – ASTM Level 2**

Primary Predicate

510K Number: K111402
Kimberly Clark Corporation
Device Name: Surgical Mask
Model: KC200 (ASTM Level 2)

- **Model GFM43A – ASTM Level 3**

Primary Predicate

510K Number: K111402
Kimberly Clark Corporation
Device Name: Surgical Mask
Model: KC200 (ASTM Level 2)

Additional Predicate

510K Number: K111402
Kimberly Clark Corporation
Device Name: Surgical Mask
Model: KC300 (ASTM Level 3)

H. Comparisons with Predicate Devices:

Model GFM31A – ASTM Level 1

	Proposed Device	Primary Predicate	Additional Predicate	Result
Manufacturer	Little Rapids Corporation	Kimberly Clark Corporation	U-Play Products Corporation	-
510K Number	K220377	K111402	K202137	-
Product Common Name(s)	Procedure Mask	Surgical Mask	Disposable Medical Mask	Similar
Model Number	GFM31A	KC200	Y01	-
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended Use	The Procedure 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. Both models are single use, disposable devices, provided non-sterile.	The Kimberly-Clark, K0200 and KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	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. 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.	Same
Design Features	Ear Loops, Flat Pleated, 3 layers, Nose Piece or No Nose Piece	4 Ply, Ear Loops, Flat-Pleated or Tie-On Style	Ear Loops, Flat Pleated, 3 layers	Similar

Materials & Design				
Outer Facing Layer	Polypropylene Spunbond	Polypropylene Spunbond	Spun-bond polypropylene	Same
Middle (Filter) Layer	Polypropylene Meltblown Filter	Melt Blown Polypropylene Filter	Melt blown polypropylene filter	Same
Inner Facing Layer	Polypropylene Spunbond	Polyester Cellulose	Spun-bond polypropylene	Similar/Same
Nose Piece (When Applicable)	PVC Coated Steel Wire	Malleable	Polypropylene + steel wire	Similar
Ear loops	White, Nylon/Spandex, Latex Free	Polyester/Lycra Knitted	Nylon and Spandex; elastic nonwoven fabrics (spun-bond polypropylene and elastic body)	Same
Color	Blue	Blue	Blue	Same
Dimension (Length)	6.875” (+ 0.25”, - 0.125”)	6.5” ± 0.75”	175 ± 10mm	Same
Dimension (Width)	3.75” (± 0.125”)	4” ± 07.5”	95 ± 10mm	Same
OTC Use	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use	Single Use, Disposable	Same
ASTM F2100 Level	Level 1	Level 2	Level 1	Similar/Same
Performance Testing Comparison				
Fluid Resistance Performance ASTM F1862	32 out of 32 passed at 80 mmHg, 3 lots	Meets Performance Requirements at 120 mm Hg	32 out of 32 pass at 80 mmHg, 3 lots	All Meet Requirements
Particulate Filtration Efficiency ASTM F2299	99.89%, 99.84%, 99.80%	98.4%	99.12%, 99.45%, 99.56%	All Meet Requirements
Bacterial Filtration Efficiency ASTM F2101	99.80%, 99.71%, 99.81%	99.7%	99.92%, 99.93%, 99.92%	All Meet Requirements
Differential Pressure (Delta P) EN 14683 Annex C	4.4 mmH_2O/cm^2, 4.7 mmH_2O/cm^2, 4.7 mmH_2O/cm^2	4.50mmH_2O/cm^2	3.0mmH_2O/cm^2, 4.2mmH_2O/cm^2, 3.7mmH_2O/cm^2	All Meet Requirements
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	All Meet Requirements

Biocompatibility	ISO 10993	ISO 10993	ISO 10993	All Meet Requirements
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.	All Meet Requirements
Irritation	Under the conditions of the study, the device is non-irritating*	Non-Irritating	Under the conditions of the study, the device is non-irritating.	All Meet Requirements
Sensitization	Under the conditions of the study, the device is non-sensitizing*	Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing	All Meet Requirements

* Model GFM31A ASTM Level 1 mask uses the same materials as model GFM42A ASTM Level 2 mask and GFM43A ASTM Level 3 mask. Since the Level 2 and Level 3 masks include one (1) additional layer of spunbond material, these masks are considered the "worst case" models for biocompatibility testing and were subjected to all tests. The ASTM Level 1 mask was tested for Cytotoxicity only.

** Coloring in Spunbond occurs at the resin level and is a permanent part of the extruded fiber structure. Color is not known to make a difference in performance.

Model GFM42A – ASTM Level 2

	Proposed Device	Primary Predicate	Result
Manufacturer	Little Rapids Corporation	Kimberly Clark Corporation	-
510K Number	Not yet assigned	K111402	-
Product Common Name(s)	Procedure Mask	Surgical Mask	Similar
Model Number	GFM42A	KC200	-
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended Use	The Procedure Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate	The Kimberly-Clark, K0200 and KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of	Same

	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.	microorganisms, body fluids, particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	
Design Features	Ear Loops, Flat Pleated, 4 layers	4 Ply, Ear Loops, Flat-Pleated or Tie-On Style	Same
Materials & Design			
Outer Facing Layer	Polypropylene Spunbond	Polypropylene Spunbond	Same
Secondary Outer Layer	Polypropylene Spunbond	Polypropylene Spunbond	Same
Middle (Filter) Layer	Polypropylene Meltblown Filter	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Polypropylene Spunbond	Polyester Cellulose	Similar
Nose Piece	PVC Coated Steel Wire	Malleable	Similar
Ear loops	White, Nylon/Spandex, Latex Free	Polyester/Lycra Knitted	Same
Color	Blue	Blue	Same
Dimension (Length)	6.875” (+ 0.25”, - 0.125”)	6.5” ± 0.75”	Same
Dimension (Width)	3.75” (± 0.125”)	4” ± 07.5”	Same
OTC Use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use	Same
ASTM F2100 Level	Level 2	Level 2	Same
Performance Testing Comparison			

Fluid Resistance Performance ASTM F1862	32 out of 32 passed at 160 mm Hg, 3 lots	Meets Performance Requirements at 120 mm Hg	Both Meet Requirements
Particulate Filtration Efficiency ASTM F2299	99.84%, 99.85%, 99.87%	98.4%	Both Meet Requirements
Bacterial Filtration Efficiency ASTM F2101	99.8%, 99.7%, 99.7%	99.7%	Both Meet Requirements
Differential Pressure (Delta P) EN 14683 Annex C	4.7 mmH_2O/cm^2, 5.0 mmH_2O/cm^2, 5.0 mmH_2O/cm^2	4.50mmH_2O/cm^2	Both Meet Requirements
Flammability 16 CFR 1610	Class 1	Class 1	Both Meet Requirements
Biocompatibility	ISO 10993	ISO 10993	Both Meet Requirements
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Non-Cytotoxic	Both Meet Requirements
Irritation	Under the conditions of the study, the device is non-irritating*	Non-Irritating	Both Meet Requirements
Sensitization	Under the conditions of the study, the device is non-sensitizing*	Non-Sensitizing	Both Meet Requirements

* Model GFM31A ASTM Level 1 mask uses the same materials as model GFM42A ASTM Level 2 mask and GFM43A ASTM Level 3 mask. Since the Level 2 and Level 3 masks include one (1) additional layer of spunbond material, these masks are considered the "worst case" models for biocompatibility testing and were subjected to all tests. The ASTM Level 1 mask was tested for Cytotoxicity only.

** Coloring in Spunbond occurs at the resin level and is a permanent part of the extruded fiber structure. Color is not known to make a difference in performance.

GFM43A – ASTM Level 3

Device	Proposed Device	Primary Predicate	Additional Predicate	Result
Manufacturer	Little Rapids Corporation	Kimberly Clark Corporation	Kimberly Clark Corporation	-
510K Number	Not yet assigned	K111402	K111402	-
Product Common Name(s)	Procedure Mask	Surgical Mask	Surgical Mask	Similar
Model Number	GFM43A	KC200	KC300	-
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended Use	The Procedure 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 Kimberly-Clark, K0200 and KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	The Kimberly-Clark, KC200 and KC300 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	Same
Design Features	Ear Loops, Flat Pleated, 4 layers	4 Ply, Ear Loops, Flat-Pleated or Tie-On Style	4 Ply, Ear Loops, Flat-Pleated or Tie-On Style	Same
Materials & Design				
Outer Facing Layer	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Same

Secondary Outer Layer	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Same
Middle (Filter) Layer	Polypropylene Meltblown Filter	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Spun-bond polypropylene	Polyester Cellulose	Polyester Cellulose	Same
Nose Piece	PVC Coated Steel Wire	Malleable	Malleable	Similar
Ear loops	White, Nylon/Spandex, Latex Free	Polyester/Lycra Knitted	Polyester/Lycra Knitted	Same
Color	Blue	Blue	Orange	Same/ Different**
Dimension (Length)	6.875" (+ 0.25", - 0.125")	6.5" ± 0.75"	6.5" ± 0.75"	Same
Dimension (Width)	3.75" (± 0.125")	4" ± 07.5"	4" ± 07.5"	Same
OTC Use	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use	Single Use	Same
ASTM F2100 Level	Level 3	Level 2	Level 3	Same
Performance Testing Comparison				
Fluid Resistance Performance ASTM F1862	32 out of 32 passed at 160 mm Hg, 3 lots	Meets Performance Requirements at 120 mm Hg	Meets Performance Requirements at 160 mm Hg	All Meet Requirements
Particulate Filtration Efficiency ASTM F2299	99.84%, 99.85%, 99.87%	98.4%	98.4%	All Meet Requirements
Bacterial Filtration Efficiency ASTM F2101	99.8%, 99.7%, 99.7%	99.7%	99.7%	All Meet Requirements
Differential Pressure (Delta P) EN 14683 Annex C	4.7 mmH_2O/cm^2, 5.0 mmH_2O/cm^2, 5.0 mmH_2O/cm^2	4.50mmH_2O/cm^2	3.20mmH_2O/cm^2	All Meet Requirements
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	All Meet Requirements
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	All Meet Requirements

Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Non-Cytotoxic	Non-cytotoxic	All Meet Requirements
Irritation	Under the conditions of the study, the device is non-irritating*	Non-Irritating	Non-irritating	All Meet Requirements
Sensitization	Under the conditions of the study, the device is non-sensitizing*	Non-Sensitizing	Non-sensitizing	All Meet Requirements

* Model GFM31A ASTM Level 1 mask uses the same materials as model GFM42A ASTM Level 2 mask and GFM43A ASTM Level 3 mask. Since the Level 2 and Level 3 masks include one (1) additional layer of spunbond material, these masks are considered the "worst case" models for biocompatibility testing and were subjected to all tests. The ASTM Level 1 mask was tested for Cytotoxicity only.

** Coloring in Spunbond occurs at the resin level and is a permanent part of the extruded fiber structure. Color is not known to make a difference in performance.

I. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as the same or similar 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)] Submission issued on March 5, 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

Note – The ASTM (performance) tests noted above were conducted in triplicate on samples obtained from three non-consecutive production lots.

J. Clinical Test Conclusion

No clinical study is included in this submission.

K. Conclusion

Based on the nonclinical tests performed, the subject devices are as safe, as effective, and perform as well as the legally marketed primary predicate device Kimberly Clark Corporation KC200 cleared under K111402, and additional predicate devices U-Play Products Corporation Y01 cleared under K202137 and Kimberly Clark Corporation KC300 cleared under K111402.