November 14, 2021

SpinTech LLC
W. Victoria Rogers
Owner
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783

Re: K212109
Trade/Device Name: Spin Care Disposable Protective Mask Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 9, 2021
Received: August 16, 2021

Dear W. Rogers:

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 Clarence W. Murray III, Ph.D.
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)*
K212109

Device Name
Spin Care Disposable Protective Mask Level 3

Indications for Use *(Describe)*
Spin Care Disposable Protective Mask Level 3 is intended for to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These protective 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.

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510(k) Summary K212109

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Spin Care Disposable Protective Mask Level 3, 510(k) premarket notification.

Sponsor:	SpinTech LLC 1920 Flintstone Drive Statesville, North Carolina 28677 Establishment Registration Number: 3016872494
Contact Person:	Jim Jean Reliability Manager Telephone: (704-929-3596)
Designated Submission Correspondent:	W. Victoria Rogers Rogers Consulting 11110 Arranmore Cove Roanoke, Indiana 46783 574-265-8356
Date:	9 November 2021
Subject Device:	Spin Care Disposable Protective Mask Level 3
Common Name:	Surgical Mask
Classification Name:	Surgical Mask
Product Code:	FXX
Regulation Number:	(21 CFR 878.4040)
Review Panel:	General & Plastic Surgery
Regulation Class:	Class II
Predicate Devices:	Freudenberg Surgical Mask (K210063)
Device Description:	The Spin Care Disposable Protective Mask Level 3 is a single use three-layer level 3 surgical mask. It houses a melt blown polypropylene filter between an outer and inner layer of spunbond polypropylene that covers the nose and mouth of the end user and held in place by a pliable nose piece and ear loops. The mask is provided white, non-sterile and is flat-pleated. Contact duration is less than 24 hours. This device is not made with natural rubber latex.

510(k) Summary K212109

Intended Use and Indications for Use:

The Spin Care Disposable Protective Mask Level 3 is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These protective 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.

510(k) Summary K212109

Summary of Technological Characteristics: The rationale for substantial equivalence is based on consideration of the following characteristics:

	Spin Care Disposable Protective Mask Level 3 K212109	**Predicate device: Freudenberg Surgical Mask K210063**	**Remarks**
Intended Use/ Indications for Use	The Spin Care Disposable Protective Mask Level 3 is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These protective 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 Freudenberg Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is 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 nonsterile.	Same
Outer Materials	Polypropylene spunbond	Spun-bond polypropylene	Same
Filter Media	Polypropylene meltdown	Melt blown polypropylene	Same
Inner Material	Polypropylene spunbond	Spun-bond polypropylene	Same
Nose Piece	Malleable aluminum wire	Malleable polyethylene coated wire	Similar
Ear Loops	Polyester	Polyester spandex blend	Similar
Dimensions	Length: 175mm Width: 95mm	Length: 175 mm +/- 1mm Width: 95 mm +/- 1mm	Same
Mask Style	Flat-pleated, 3 layers	Flat-pleated, 3 layers	Same
Color	White	White	Same
Sterilization	Non-sterile	Non-sterile	Same

Performance Testing ASTM F2100 – Level 3			
Fluid resistance **ASTM F1862**	Passed at 160mmHg	Passed at 160mmHg	Same
Particle Filtration Efficiency **ASM F2299**	Passed ≥98%	Passed ≥98%	Same
Bacterial Filtration Efficiency **ASTM F2101**	Passed ≥98%	Passed ≥98%	Same
Flammability Class **16 CFR 1610**	Class I Non-Flammable	Class I Non-Flammable	Same
Differential Pressure Delta-P **EN14683**	Passed <6.0 mmH2O/cm2	Passed <6.0 mmH2O/cm2	Same
Biocompatibility Testing			
Cytotoxicity **ISO 10993-5**	Comply with ISO 10993-5. Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic	Non-cytotoxic	Same
Irritation **ISO 10993-10**	Comply with ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-irritating	Non-irritating	Same
Sensitization **ISO 10993-10**	Comply with ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-sensitizing	Non-sensitizing	Same

510(k) Summary K212109

Summary of Performance Data

- **Nonclinical**

The product was tested in alignment with "Guidance for Industry and FDA Staff – Surgical Masks – Premarket Notification [510(k)] Submission" Guidance Document

Performance testing was conducted using 32 samples per lot, 3 non-consecutive lots to demonstrate the safety and efficacy of the Spin Care Disposable Protective Mask Level 3 in support of substantial equivalence.

Standard Number and Name	Test Criteria for Level 3	Result
ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) Fluid Resistance Performance	Pass at 160mg	Pass at 160mmHg
ASTM F2299 Particulate Filtration Efficiency (PFE)	≧98%	Passed ≥98%
ASTM F2101 Bacterial Filtration Efficiency (BFE)	≧98%	Passed ≥98%
Differential Pressure (Delta P) MIL-M-36954C (Military Std)	<6.0 mm H_2O /cm^2	Passed <6.0 mmH2O/cm2
16 CFR 1610 Flammability	Class 1 (≧ 3.5 seconds)	Passed - Class 1 Non-Flammable

Test Report Name and Number	Test Criteria	Results
In Vitro Cytotoxicity Test –ISO 10993-5 Nelson Report No. 135543-S01 / Test Article 61920AVGOL	ISO 10993-5 Part 5: Tests for in vitro cytotoxicity	No potential cytotoxicity
Intracutaneous Injection Test ISO Irritation 10993-10 Final GLP Report: 20-02536-G2 Nelson Report No. 1315542-S01 Test Article 61920AVGOL	ISO 10993-10 Part 10: Tests for irritation and skin sensitization.	No significantly greater biological reaction than the sites injected with the control article.

Kligman Maximization Test **Sensitization ISO 10993-10** Final GLP Report: 20-02536-G1 Nelson Report No. 1315541-S01 Test Article 61920AVGOL	ISO 10993-10 Part 10: Tests for irritation and skin sensitization.	The test article was classified as a non-sensitizer.

- **Clinical Tests:**
  - No clinical tests were performed.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Spin Care Disposable Protective Mask Level 3 is as safe, as effective, and performs as well as or better than the predicate devices.