March 18, 2021

SpinTech LLC
% W. Victoria Rogers
Regulatory Affairs Consultant
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783

Re: K201624
Trade/Device Name: Spin Care Disposable Protective Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 8, 2020
Received: December 31, 2020

Dear W. Victoria 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,

Ryan Ortega, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201624

Device Name
Spin Care Disposable Protective Mask

Indications for Use *(Describe)*
The Spin Care Disposable Protective Mask is 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.

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510(k) Summary

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 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

510(k) Number: K201624

Sponsor:
SpinTech LLC
1920 Flintstone Drive
Statesville, North Carolina 28677 USA
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 USA
574-265-8356

Date: March 9, 2021

Subject Device:
Trade Name: Spin Care Disposable Protective Mask
Common Name: Surgical Facemask

Classification Name:
- FXX– Surgical Apparel (21 CFR 878.4040)

Predicate Device(s):

K153496	Disposable Surgical Face Mask	Xiantao Rayxin Medical Products., Ltd.
K160269	Surgical Face Masks (Ear Loops and Tie-on)	SAN-M Package Co., LTD.

Purpose and Device Description:

The Spin Care Disposable Protective Mask is a single use multi-layer level 2 surgical mask. It houses a meltblown 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. Contact duration is less than 24 hours.

Intended Use and Indications for Use:

The Spin Care Disposable Protective Mask is 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.

Summary of Technological Characteristics:

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

	Spin Care Disposable Protective Mask	**Disposable Surgical Face Mask, K153496 (Primary Predicate)**	**Surgical Face Masks (Ear Loops and Tie-on), K160269**
ASTM 2100 Level Mask	2	2	2
Intended Use/ Indications for Use	The Spin Care Disposable Protective Mask is 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(s), provided non-sterile.	The 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.
Materials			
Outer Materials	Polypropylene Spunbond	Spun-bond polypropylene	Polypropylene
Filter Media	Polypropylene meltdown	Melt blown polypropylene filter	1. Polypropylene Spunbond 2. Polypropylene meltdown

Inner Material	Polypropylene Spunbond	Spun-bond polypropylene	Polypropylene
Nose Piece	Malleable metal wire	Malleable Aluminum Wire	Polyethylene coated steel wire
Ear Loops	Elastane and nylon	Ear Loop or Tie On - Polyester	Ear Loop or Tie On – Polyester Polyurethane / Polypropylene Spunbond or polyester Spunbond
Specifications	Length: 175mm Width: 95mm	Length: 175 mm +/- 1mm Width: 95 mm +/- 1mm	Length: 90 ± 3mm Width: 175 ± 5mm
Mask Style	Flat-pleated	Flat-pleated	Flat-pleated
Color	White	Blue	White or Blue
Sterilization	Non-sterile	Non-sterile	Non-sterile
Performance Testing			
ASTM F2100 – Level 2			
Fluid resistance ASTM F1862	120mm Hg - Pass	120mm Hg - Pass	120mm Hg - Pass
Particle Filtration Efficiency ASM F2299	Average 99.8% - Pass	Average 98.46% - Pass	Average 99.6% - Pass
Bacterial Filtration Efficiency ASTM F2101	Average >99.9% - Pass	Average 98.7% - Pass	Average > 98% - Pass
Flammability Class 16 CFR 1610	Class I Non-Flammable	Class I Non-Flammable	Class I Non-Flammable
Delta-P	Average 3.79mmH_2O/cm^2 (EN 14683)	Average 4.2 mmH_2O/cm^2 (MIL-M-36954C)	Average 1.6 mmH_2O/cm^2 (MIL-M-36954C)
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	Non-cytotoxic
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	Non-irritating
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	Non-sensitizing

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - The product was tested in alignment with "Guidance for Industry and FDA Staff – Surgical Masks – Premarket Notification [510(k)] Submission" Guidance Document
    - 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 F2100-19, Standard Specification For Performance Of Materials Used In Medical Face Masks
    - ASTM F1862-17, 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: European standard for 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;
    - ASTM F2299-03, Stand 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.
- **Clinical Tests:**
  - No clinical tests were performed.

Substantial Equivalence Conclusion

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