February 21, 2022

Boston Scientific Corporation
Laura Meehan
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K203548
Trade/Device Name: EndoArmor™ + Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: January 20, 2022
Received: January 21, 2022

Dear Laura Meehan:

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,

Clarence W. Murray, III, PhD
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)*
K203548

Device Name
EndoArmor™ + Surgical Gown

Indications for Use *(Describe)*
EndoArmor™+ Surgical Gowns are single-use personal protective equipment intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

EndoArmor™+ Surgical Gowns meet the respective Level 3 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

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 for EndoArmor™+ Surgical Gown
K203548

1. Submitter

Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
Marlborough, MA 01752

Contact:

Laura Meehan
Principal Regulatory Specialist
Phone: (508) 382-0442
E-mail: Laura.Meehan@bsci.com

Date Prepared: January 20, 2022

2. Device

Trade Name:	EndoArmor™+ Surgical Gown
Common Name:	Surgical Gown
Classification Name:	Surgical Apparel
Product Code:	FYA
Device Class and Panel:	Class II, General Hospital
Classification Regulation:	21 CFR §878.4040

3. Predicate Devices

Trade Name:	Medline Level 3 Surgical Gown (Sirus Non-Reinforced)
Manufacturer:	Medline Industries, Inc.
Clearance Number:	K190950
Common Name:	Surgical Gown
Classification Name:	Surgical Apparel
Product Code:	FYA
Device Class and Panel:	Class II, General Hospital
Classification Regulation:	21 CFR §878.4040

4. Device Description

EndoArmor™+ Surgical Gowns are intended to be worn by health care professionals as personal protective equipment to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

The EndoArmor™+ Surgical Gown is constructed from a polyethylene film laminated with nonwoven spunbond polypropylene that provides AAMI Level 3 liquid barrier performance in

the critical zones. The EndoArmor™+ Surgical Gown back was designed to allow for airflow and breathability to support user comfort. The back of the gown is constructed from spunbond polypropylene and is non-protective.

The EndoArmor™+ Surgical Gown is single-use, one-size fits most personal protective equipment supplied non-sterile with sterilization instructions and validated sterilization parameters to enable the end-user to sterilize the gown prior to being used in sterile surgical procedures.

5. Indications for Use

EndoArmor™+ Surgical Gowns are single-use personal protective equipment intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

EndoArmor™+ Surgical Gowns meet the respective Level 3 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

6. Technological Characteristics Comparison of the proposed device and predicate device

Table 5-1: Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	EndoArmor™ + Surgical Gown	Medline Level 3 Surgical Gown (Sirus Non-Reinforced)	N/A
510(k) Reference	K203548	K190950	N/A
Product Owner	Boston Scientific Corporation	Medline Industries, Inc.	N/A
Regulation Number	21 CFR §878.4040	21 CFR §878.4040	Identical
Product Code	FYA	FYA	Identical

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Intended Use	EndoArmor™+ Surgical Gowns are single-use personal protective equipment intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. EndoArmor™+ Surgical Gowns meet the respective Level 3 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.	Medline Level 3 Surgical Gowns (Sirus Non-Reinforced) are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. Medline Level 3 Surgical Gowns (Sirus Non-Reinforced) meet the respective Level 3 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.	Similar
Color	Blue	Blue	Identical
Design Features	Fabric Non-Reinforced Hook and Loop Closure at neck Belt Ties Knit Cuffs Standard Sleeves	Fabric Non-Reinforced Hook and Loop Closure at neck Belt Ties Knit Cuffs Standard Sleeves	Identical
Sizes	One-size fits most	Small to XXXX-Large	Similar
Materials	Front/Sleeves: Polyethylene Film Laminated with Nonwoven Spunbond Polypropylene Back: Nonwoven Spunbond Polypropylene	Nonwoven SMS Polypropylene/Polyolefin	Similar
Critical Zone Performance Specifications	AAMI Level 3 Barrier Protection	AAMI Level 3 Barrier Protection	Identical

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Prescription vs. OTC	OTC	OTC	Identical
Contact Duration	Surface, Intact, < 24 hours	Surface, Intact, < 24 hours	Identical
Sterile vs. Non-Sterile	Sold as single-use, non-sterile to end user with sterilization instructions and validated EtO sterilization method	Sterile (Ethylene Oxide) or sold as bulk single-use, non-sterile to re-packager/re-labeler establishments for further packaging and sterilization using the validated EtO sterilization method according to ISO 11135-1 prior to being provided to the end user	Identical
Single Use vs. Reusable	Single Use	Single Use	Identical
Biocompatibility	Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10.	Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10.	Identical
Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets requirements of Flame Resistant CPSC 1610 Class 1	Identical

7. Performance Data

The final proposed finished device was tested in accordance with *Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes*, August 1993, *Guidance for Industry and FDA Staff - Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings* issued by the FDA on December 9, 2015 and *ANSI/AAMI PB70:2012, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*.

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	The purpose of this test methodology is to evaluate the cytotoxicity endpoint.	Under the test conditions, the subject device must be non-cytotoxic per ISO 10993-5.	Pass.
ISO 10993-7, Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals	The purpose of this test methodology is to evaluate the EO/ECH residuals.	Under the test conditions, the EO/ECH residual levels of the subject device must be below the maximum allowable limits for adult patient populations based on body mass per ISO 10993-7.	Pass.

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	The purpose of this test methodology is to evaluate the irritation and skin sensitization endpoint.	Under the test conditions, the subject device must be non-irritating and non-sensitizing per ISO 10993-10.	Pass.
ASTM F2407-20, Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	The purpose of this test methodology is to evaluate the standard specification for surgical gown.	Under the test conditions, the subject device must meet the required tensile strength, tear resistance, and seam strength per ASTM F2407-20.	Pass.
AATCC TM42, Test Method for Water Resistance: Impact Penetration	The purpose of this test methodology is to evaluate the impact penetration endpoint.	Under the test conditions, the subject device must meet the required resistance to the penetration of water per ANSI/AAMI PB70.	Pass.
AATCC TM127, Test Method for Water Resistance: Hydrostatic Pressure Test	The purpose of this test methodology is to evaluate the Hydrostatic Pressure Test endpoint.	Under the test conditions, the subject device must meet the required resistance to the penetration of water under hydrostatic pressure per ANSI/AAMI PB70.	Pass.
ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	The purpose of this test methodology is to evaluate the Grab Test endpoint.	Under the test conditions, the subject device must meet the required tensile strength per ASTM F2407-20.	Pass.
ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	The purpose of this test methodology is to evaluate the Tearing Strength of Fabrics by Trapezoid Procedure.	Under the test conditions, the subject device must meet the required tear resistance per ASTM F2407-20.	Pass.
ASTM D1683 / D1683M-17, Standard Test Method for Failure in Sewn Seams of Woven Fabrics	The purpose of this test methodology is to evaluate the Standard Test Method for Failure in Sewn Seams of Woven Fabrics	Under the test conditions, the subject device must meet the required seam strength per ASTM F2407-20.	Pass.
16 CFR Part 1610, Standard for the Flammability of Clothing Textiles	The purpose of this test methodology is to evaluate the Flammability of Clothing Textiles.	Under the test conditions, the subject device must meet the Class I flammability standard per 16 CFR Part 1610.	Pass.

8. Conclusion

The conclusions drawn from the nonclinical tests that demonstrate that the EndoArmor™+ Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed device.