DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-000

August 26, 2014

Stryker Instruments
Ms. Julia L. Helgeson
Senior Regulatory Representative
4100 E. Milham Ave
Kalamazoo, MI 49001

Re: K141095
Trade/Device Name: Stryker Steri-Shield Flyte Hybrid Togas
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: July 30, 2014
Received: July 31, 2014

Dear Ms. Helgeson,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141095

Device Name
Styker Steri-Shield Flyte Hybrid Togas

Indications for Use *(Describe)*
The Stryker Steri-Shield Flyte Hybrid Togas are components of a personal protection system and are intended to protect the patient, healthcare personnel, and operating room personnel against contamination, exposure of infectious bodily fluids, the transfer of microorganisms and particulate material.

The togas are sterile and single use only.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4100 E. Milham Ave.
Kalamazoo, MI 49001
t: 269 329 7000 f: 269 389 5412
www.stryker.com

K141095

510(k) Summary

510(k) Owner: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-329-7000
(f) 269-389-5412

Contact Person: Julia L. Helgeson
Sr. Regulatory Affairs Representative

Registration Number: 1811755

Date Summary Prepared: June 25, 2014

Trade Name(s): Stryker Steri-Shield Flyte Hybrid Togas

Common Name: Surgical Apparel

Classification Data:

Product Code	Device	Regulation Number	Class	Review Panel
FYA	Gown, Surgical	21 CFR 878.4040	II	General & Plastic Surgery

Reason for 510(k) Submission: **Special 510(k):** Device Modifications with no change to fundamental scientific technology or intended use.

Device Modification: Stryker submits this **Special 510(k): Device Modification** for our Steri-Shield Flyte Togas. The modifications are as follows:

- Change in material utilized in hood region of toga
- Change in material formulation of barrier material
- Dimensional changes for user fit
- Minor design modifications to component attachment methods

The modification changes neither the intended use, the indications for use, nor the fundamental scientific technology.

Predicate SE Device(s): Stryker Steri-Shield Flyte Togas (K073017)

Indications for Use: The Stryker Steri-Shield Flyte Hybrid Togas are components of a personal protection system and are intended to protect the patient, healthcare personnel, and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganisms and particulate material. The togas are sterile and single-use only.

Device Description: The Steri-Shield Flyte Hybrid Togas are single use, sterile, disposable devices that comprise part of the Steri-Shield Flyte Hybrid Personal Protection System. They are intended to be worn by healthcare personnel to protect the patient and healthcare

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t: 269 329 7000 f: 269 389 5412
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personnel against contamination, exposure of infectious bodily fluids and the transfer of microorganisms and particulate material. The devices are prescription use.

Device Models:

Description	Part Numbers
Stryker Steri-Shield Flyte Hybrid Zippered Togas, Standard Lens	0408-8X1-000 Series
Stryker Steri-Shield Flyte Hybrid Zippered Togas, Peel Away Lens	0408-8X1-100 Series
Stryker Steri-Shield Flyte Hybrid Pullover Togas	0408-7X1-000 Series

Performance Data (Non Clinical Tests): Results of performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the Steri-Shield Flyte Hybrid Togas are sufficient for their intended use and support a determination of substantial equivalence.

Summary of Performance Testing

Biocompatibility testing was performed on the subject device in accordance with ANSI/AAMI/ISO 10993-1:2009: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing and AAMI Standards and Recommended Practices, Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices. Results of testing validate the subject device is non-cytotoxic, non-sensitizing, and a negligible irritant.

Stryker Steri-Shield Flyte Hybrid Togas will be available only in sterile packaged form. The sterile product will be terminally sterilized using ethylene oxide (EO). The sterilization method was validated and performed in accordance with ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide. A sterility assurance level of 10^{-6} has been validated for this product.

Comparison to Predicate Device:

Description	Stryker Steri-Shield Flyte Togas (K073017) (Predicate)	Stryker Steri-Shield Flyte Hybrid Togas (Subject)	Explanation of Difference
Classification/ Regulation	Class II	Class II	Identical
Regulation	21 CFR 878.4040 Surgical Apparel	21 CFR 878.4040 Surgical Apparel	Identical
Product Code	FYA	FYA	Identical

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Description	Stryker Steri-Shield Flyte Togas (K073017) (Predicate)	Stryker Steri-Shield Flyte Hybrid Togas (Subject)	Explanation of Difference
Intended Use	The Stryker Steri-Shield Flyte Togas are components of a personal protection system and are intended to protect the patient, health care personnel and operating room personnel against contamination, exposure of infectious bodily fluids, the transfer of microorganisms and particulate materials.	The Stryker Steri-Shield Flyte Hybrid Togas are components of a personal protection system and are intended to protect the patient, health care personnel and operating room personnel against contamination, exposure of infectious bodily fluids, the transfer of microorganisms and particulate materials. The togas are sterile and single use only.	Identical
Target Population	Operating room personnel	Operating room personnel	Identical
Conditions for Use	Single Use/Disposable	Single Use/Disposable	Identical
Materials			
Hood Region	Polypropylene and polyester	Polypropylene	Steri-Shield Flyte Hybrid products utilizes a more breathable material in the hood region.
Filter	Polypropylene and Acrylic	Polypropylene and Acrylic	Identical
Lens: Standard (Non-Peelaway)	Clear Polycarbonate	Clear Polycarbonate	Identical
Lens: Peelaway	Clear PET Laminate	Clear PET Laminate	Identical
Front and Sleeves (Barrier Material)	Polypropylene and polyester	Polypropylene and polyester	Similar. Steri-Shield Flyte Hybrid front and sleeves use an improved grade of the material, which increases manufacturing efficiencies.
Back and Shoulder Ties	polypropylene	polypropylene	Identical
Waist Ties	Polypropylene and polyester	Polypropylene and polyester	Identical
Cuffs	Polyester	Polyester	Identical
Zipper	Polyester, Nylon, and Vinyl	Polyester, Nylon, and Vinyl	Identical
Zipper Guard	polypropylene	polypropylene	Identical
Color	Hood region material: Blue Front/Sleeve material: Blue Back material: Blue Filter material: White Cuffs: White	Hood region material: Light blue Front/Sleeve material: Blue Back material: Blue Filter material: White Cuffs: White	Similar. Steri-Shield Flyte Hybrid hood region material is light blue in color instead of blue.
Physical/ Mechanical Specifications			

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Description	Stryker Steri-Shield Flyte Togas (K073017) (Predicate)	Stryker Steri-Shield Flyte Hybrid Togas (Subject)	Explanation of Difference
Lint Level (ISO 9073 part 10)	Compliant - Pass	Compliant - Pass	Specification met. Steri-Shield Flyte Hybrid Togas use a different hood region material. The filter material was not tested as part of the initial 510k but was tested for the Steri-Shield Flyte Hybrid 510k.
Tensile Strength (BS EN 29073-3)	Compliant - Pass	Compliant - Pass	Specification met. Steri-Shield Flyte Hybrid hood region material has a lower tensile strength, but it still meets the specification. The filter material was not tested as part of the initial 510k but was tested for the Steri-Shield Flyte Hybrid 510k.
Tear Resistance (Flyte Hybrid: ASTM D 5587-08; Flyte: ASTM D 5733)	Compliant - Pass	Compliant - Pass	Specification met. ASTM D5733 was withdrawn in 2008; therefore, a different test standards were followed. The filter material was not tested as part of the initial 510k, but was tested for the Steri-Shield Flyte Hybrid 510k.
Evaporative resistance (ASTM F 1868)	Not Previously Tested	Compliant - Pass	Specifications met. Evaporative Resistance was not previously tested as part of the initial Steri-Shield Flyte 510k.
Bacterial Filtration Efficiency per ASTM F2101-07	Compliant - Pass	Compliant - Pass	Specifications met.
Particulate Filtration Efficiency per ASTM F2299-03	Compliant - Pass	Compliant - Pass	Specifications met.
Barrier Performance			

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Description	Stryker Steri-Shield Flyte Togas (K073017) (Predicate)	Stryker Steri-Shield Flyte Hybrid Togas (Subject)	Explanation of Difference
Viral Penetration (per ASTM F1671) Level 4 Critical Zone as defined in AAMI/ANSI PB70	Hood region material: Pass requirements for Level 4 Protection. Front/Sleeve material: Pass requirements for Level 4 Protection. Sleeve Seam: Pass requirements for Level 4 Protection.	Hood region material: Material not designed to meet Level 4 protection and was not tested for viral penetration Front/Sleeve material: Pass requirements for Level 4 Protection. Sleeve Seam: Pass requirements for Level 4 Protection.	Specifications met.
Water Resistance: Impact Penetration (per AATCC 42) Level 1 Critical Zone as defined in AAMI/ANSI PB70	Hood region Material: Pass requirements for Level 1 Protection. Back material: Pass requirements for Level 1 Protection. All other protective seams: Pass requirements for Level 1 Protection.	Hood region Material: Pass requirements for Level 1 Protection. Back material: Pass requirements for Level 1 Protection. All other protective seams: Pass requirements for Level 1 Protection.	Specifications met.
General Safety and Performance			
Biocompatibility			
in vitro cytotoxicity	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, non-cytotoxic	Identical
primary skin irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Identical
skin sensitization	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Identical
Flammability	No Flame Spread per 16 CFR Part 1610	No Flame Spread per 16 CFR Part 1610	Identical
Shelf Life	3 years	1 year	Similar – the intent is to extend the shelf life for the subject device upon successful completion of aging studies
Finished (Terminal) Product Sterilization Method	SAL 10^{-6} Terminally sterilized via Ethylene Oxide in accordance with ISO 11135-1	SAL 10^{-6} Terminally sterilized via Ethylene Oxide in accordance with ISO 11135-1	Identical
Packaging	Individually packaged in a Poly-Tyvek pouch	Individually packaged in a Poly-Tyvek pouch	Identical

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Description	Stryker Steri-Shield Flyte Togas (K073017) (Predicate)	Stryker Steri-Shield Flyte Hybrid Togas (Subject)	Explanation of Difference
Labeling	Adhesive backed label placed on carton and pouch label printed directly onto the Tyvek. Label specified part description, quantity, sterilization method, lot number, expiration date, and contact information. No known contraindications.	Adhesive backed label placed on carton and pouch label printed directly onto the Tyvek. Label specified part description, quantity, sterilization method, lot number, expiration date, and contact information. No known contraindications.	Identical

Conclusion/ Substantial Equivalence (SE) Rationale:

The Stryker Steri-Shield Flyte Hybrid Togas are substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the previously cleared Stryker Steri-Shield Flyte Togas. The products have the same fundamental scientific technology, basic design, functional characteristics and applications. The modifications introduced raise no new issues of safety and effectiveness. Therefore, the Stryker Steri-Shield Flyte Hybrid Togas are substantially equivalent to the existing predicate devices.