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Kalamazoo, MI 49001
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K140588

510(k) Summary

JUN 2 6 2014

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 Flyte Hybrid Hoods

Common Name: Surgical Apparel

Classification Data:

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

Reason for 510(k) Submission: **Special 510(k):** Device Modification to Stryker Flyte Hood material

Predicate SE Device(s): K063005, Stryker T6 Hoods and Togas

Indications for Use: The Stryker Flyte Hybrid Hoods are devices within a personal protection system and are intended to protect the patient, healthcare personnel, and operation room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganisms and particulate material. The hoods are provided sterile and for single-use only.

Device Description: The Stryker Flyte Hybrid Hoods are intended to be worn over a Flyte Helmet to provide protection to the user's face and head region during surgery. Hoods are worn in conjunction with surgical gowns where the hood material extends beyond the user's upper back and shoulders, while the surgical gown covers the lower portion of the hood up to the user's neck.

The Stryker Flyte Hybrid Hood is comprised of 3 main parts: Hood, Filter and Lens. Stryker Flyte Hybrid Hoods are available with either a standard or peel away lens.

The devices are prescription devices, provided sterile and single use only.

Hood Models: 0408-801-400 Stryker Flyte Hybrid Hood
0408-801-500 Stryker Flyte Hybrid Hood with Peelaway Lens

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Device Modification: Stryker submits this **Special 510(k): Device Modification** to request a modification for our Stryker T6 Hoods. The modification is a change to the material utilized in the hoods. Neither the lens nor the filter material has changed. The modification changes neither the intended use nor the indications for use.

Performance Data (Non Clinical Tests): Results of performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker Flyte Hybrid Hoods 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 Flyte Hybrid Hoods 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.

Additional Tests Performed as a Result of Material Change

Test Performed	Acceptance Criteria	Conclusion
CO_2 Level Inside the Hood (Internal test to aid in determining user comfort)	CO_2 Level < 5000 ppm	Pass
Flammability (16 CFR Part 1610)	No burn time or burn time ≥ 3.5 s	Pass
Linting (ISO 9073-10)	≤ 4.0 C_L	Pass
Tensile Strength (BS EN 29073-3:1992)	≥ 20 N	Pass
Water Spray Impact Penetration (AATCC Test Method 42-2007)	≤ 4.5 g	Pass
Tear Resistance (ASTM D5587-08)	Hood ≥ 2.50 lbf	Pass
	Filter ≥ 2.00 lbf	
Evaporative Resistance (ASTM F1868-12 Part B)	Hood ≤ 25.22 Pa•m²/W	Pass
Seam Strength Testing (ASTM D1683/D1683M – 11a)	Lens to Hood peel ≥ 2.00 lbf	Pass
	Lens to Hood shear ≥ 6.00 lbf	
	All other seams ≥ 4.00 lbf	

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Comparison to Predicate Device(s):

Description	Stryker T6 Hoods and Togas K063005 (Predicate)	Stryker Flyte Hybrid Hoods (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	FXY	FXY	Identical
Intended Use	The Stryker T6 Hood; T6 Hood, Peel-away; T6 Hood, S95; T6 Toga, Pullover; T6 Toga, Zippered; and the T6 Toga with Peel-away Lens, Zippered 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 Flyte Hybrid Hoods are devices within a personal protection system and are intended to protect the patient, healthcare personnel, and operation room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganisms and particulate material. The hoods are provided 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	Stryker Flyte Hybrid Hoods 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
Color	Hood region material: Blue Filter material: White	Hood region material: Light blue Filter material: White	Similar. Stryker Flyte Hybrid hood region material is light blue in color instead of blue.
Physical/ Mechanical Specifications			
Lint Level (ISO 9073 part 10)	Compliant - Pass	Compliant - Pass	Specification met. Stryker Flyte Hybrid Hoods use a different hood region material. The filter material was not tested as part of the predicate 510k but was tested for the subject 510k.

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Description	Stryker T6 Hoods and Togas K063005 (Predicate)	Stryker Flyte Hybrid Hoods (Subject)	Explanation of Difference
Tensile Strength (BS EN 29073-3)	Compliant - Pass	Compliant - Pass	Specification met. Stryker 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 predicate 510k but was tested for the subject 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, different test standards were followed. The filter material was not tested as part of the predicate 510k, but was tested for the subject 510k.
Evaporative resistance (ASTM F 1868)	Not Previously Tested	Compliant - Pass	Specifications met. Evaporative Resistance was not previously tested as part of the predicate 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			
Water Resistance: Impact Penetration (per AATCC 42) Level 1 Critical Zone as defined in AAMI/ANSI PB70	Hood Material: Pass AAMI/ANSI PB70 Requirements for Level 4 Protection.	Hood Material: Pass AAMI/ANSI PB70 Requirements for Level 1 Protection.	Specification met. Stryker Flyte Hybrid Hood material offers a lower level of protection when compared to the predicate Hood material.
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

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Description	Stryker T6 Hoods and Togas K063005 (Predicate)	Stryker Flyte Hybrid Hoods (Subject)	Explanation of Difference
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
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 Flyte Hybrid Hoods are substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the previously cleared Stryker T6 Hoods. 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 Flyte Hybrid Hoods are substantially equivalent to the existing predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-000

June 26, 2014

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

Re: K140588
Trade/Device Name: Stryker Flyte Hybrid Hoods
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXY
Dated: May 15, 2014
Received: May 27, 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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

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)*
K140588

Device Name
Stryker Flyte Hybrid Hoods

Indications for Use *(Describe)*
The Stryker Flyte Hybrid Hoods 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 devices are provided sterile and for 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)*

Sreekanth Gutala -S

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