October 16, 2024

Stryker Instruments
Susanne Galin
Chief Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K241272
Trade/Device Name: Stryker Steri-Shield 8 Surgical Hoods and Togas
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA, FXY
Dated: May 6, 2024
Received: September 17, 2024

Dear Susanne Galin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241272

Device Name

Stryker Steri-Shield 8 Surgical Hoods and Togas

Indications for Use *(Describe)*

The Stryker Steri-Shield 8 disposables, including all hood and toga models, are components of the Stryker Steri-Shield 8 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 microorganism and particulate material. The Stryker Steri-Shield 8 disposables are sterile, disposable, single-use only devices.

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

This Traditional 510(k) is submitted by:

Address: Stryker Instruments
1941 Stryker Way
Portage, MI 49002, USA
Telephone Number: 269-389-2300

510(k) Number: K241272
Date Prepared: October 16, 2024

Contact Information

Contact Name: Susanne Galin
Title: Chief Regulatory Affairs Specialist
Email: Susanne.Galin@stryker.com

Device Information

Device Proprietary Name	**Stryker Steri-Shield 8 Surgical Hoods and Togas**
Device Common Names	Gown, Surgical; Hood, Surgical
Classification	Class II
Classification Product Codes and Names	FYA- Gown, Surgical FXY- Hood, Surgical
Classification Regulation	CFR 878.4040
Review Panel	General Hospital

Predicate Device

The following are the legally marketed predicate devices for the subject devices included in this Traditional 510(k):

	Trade Name	510(k) Number	Product Code	Manufacturer
Predicate	Stryker T7 Surgical Hoods and Togas	K200493	FXY, FYA	Stryker Corporation

Device Description

The Stryker Steri-Shield 8 Surgical Personal Protective Equipment consist of Stryker Steri-Shield 8 Surgical Hoods and Steri-Shield 8 Surgical Togas.

The Stryker Steri-Shield 8 Surgical Hood is a single piece device that covers the user's head, neck, and shoulder region and is intended to be worn with commercially available sterile surgical gowns. The Steri-Shield 8 Hoods are available with Standard (NPA), Peel Away (PA) and Anti-Reflective (AR) face shield options.

The Stryker Steri-Shield 8 Surgical Togas are a single piece device that covers the user's head, neck, arms, torso, and upper legs region. The Stryker Steri-Shield 8 Surgical Togas is offered in three configurations: Steri-Shield 8 Pullover Togas, Steri-Shield 8 Zippered Togas, and Steri-Shield 8 Tie Back Togas.

Indications for Use

The Stryker Steri-Shield 8 disposables, including all hood and toga models, are components of the Stryker Steri-Shield 8 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 microorganism and particulate material. The Stryker Steri-Shield 8 disposables are sterile, disposable, single-use only devices.

Comparison to Predicate Device

Characteristic	Subject Device: Stryker Steri-Shield 8 Surgical Hoods and Togas	Predicate Device: Stryker T7 Surgical Hoods and Togas (K200493)	Equivalence Assessment
Proprietary Name	Stryker Steri-Shield 8 Surgical Hoods and Togas	Stryker T7 Surgical Hoods and Togas	*Branding name, line extension*
Product Classification/ Regulation	Class II 21 CFR 878.4040 Surgical Apparel	Class II 21 CFR 878.4040 Surgical Apparel	*Identical*
FDA Product Codes	FXY, FYA	FXY, FYA	*Identical*

Indications for Use Statement	The Stryker Steri-Shield 8 disposables, including all hood and toga models, are components of the Stryker Steri-Shield 8 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 microorganism and particulate material. The Stryker Steri-Shield 8 disposables are sterile, disposable, single-use only devices.	The Stryker T7 Surgical Personal Protective Equipment Hoods and Togas are components of Stryker T7 Personal Protective Equipment (PPE). These surgical devices are intended to protect the patient, health care personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Stryker T7 Surgical Personal Protective Equipment Hoods and Togas are sterile, single use only devices.	*Identical (except for branding)*
Primary User Population	Healthcare Professional operating within an environment requiring barrier protection.	Healthcare Professional operating within an environment requiring barrier protection.	*Identical*
Hood and Toga Models	Hood, Pullover Toga, Zippered Toga, Tie Back Toga	Hood, Pullover Toga, Zippered Toga	*Similar*

Characteristic	Subject Device: Stryker Steri-Shield 8 Surgical Hoods and Togas	Predicate Device: Stryker T7 Surgical Hoods and Togas (K200493)	Equivalence Assessment
Shelf Life	1.5 years	3 years	*Different*
Available Sizes	Hood Single Size Only Toga: Large, X Large, 2X Large, 3X Large	Hood Single Size Only Toga: Large, X Large, 2X Large, 3X Large	*Identical*
Conditions for Use	Single Use Only	Single Use Only	*Identical*
Raw Materials			
Face Shield Standard	Clear PC	Clear PC	*Identical*
Face Shield Peel Away	Clear PET Laminate	Clear PET Laminate	*Identical*
Face Shield Anti-Reflective	Clear PET with Anti-Reflective Coating	Clear PET with Anti-Reflective Coating	*Identical*
Hood Side/Back	MB20: Electrostatically charged melt blown polypropylene with spunbond scrim on both sides	MB20: Electrostatically charged melt blown polypropylene with spunbond scrim on both sides	*Identical*
Filter Material	Polypropylene and Acrylic; TS030Plus	Polypropylene and Acrylic; TS050Plus	*Similar*
Hood Front	BVB - trilaminate with polyethylene and polyester outer layers with monolithic film in the middle	BVB - trilaminate with polyethylene and polyester outer layers with monolithic film in the middle	*Identical*
Toga Bodice Back Panel	SMS: Tri-laminate polypropylene nonwoven fabric with layers of spunbond, meltblown and spunbond	SMS: Tri-laminate polypropylene nonwoven fabric with layers of spunbond, meltblown and spunbond	*Identical*
Toga Front	BVB - trilaminate with polyethylene and polyester outer layers with monolithic film in the middle	BVB - trilaminate with polyethylene and polyester outer layers with monolithic film in the middle	*Identical*
Toga Sleeves	BVB - trilaminate with polyethylene and polyester outer layers with monolithic film in the middle	BVB - trilaminate with polyethylene and polyester outer layers with monolithic film in the middle	*Identical*
Toga Sleeve Cuffs	100% Type 310 Polyester	100% Type 310 Polyester	*Identical*
Thread	Polyester	Polyester	*Identical*

Characteristic	Subject Device: Stryker Steri-Shield 8 Surgical Hoods and Togas	Predicate Device: Stryker T7 Surgical Hoods and Togas (K200493)	Equivalence Assessment
Weave and Thread Count	All materials are non-woven	All materials are non-woven	*Identical*
Barrier Performance			
Critical Zone Barrier Performance: **Gown**	ASTM F1671 testing - BVB & Sleeve Seam: passes requirements for PB70 Level 4 protection	ASTM F1671 testing - BVB & Sleeve Seam: passes requirements for PB70 Level 4 protection	*Both meet acceptance criteria*
Non-Critical Barrier Performance: **Gown**	All materials and seams of Togas pass AATCC Test Method 42 Per AAMI/ANSI PB70 (<4.5g)	All materials and seams of Togas pass AATCC Test Method 42 Per AAMI/ANSI PB70 (<4.5g)	*Both meet acceptance criteria*
Exempt Barrier Performance: **Hood**	All materials and seams are non-protective	All materials and seams are non-protective	*Both meet acceptance criteria*
Physical Performance			
Flammability per 16 CFR Part 1610	Class 1	Class 1	*Both meet acceptance criteria*
Water Spray Impact per AATCC42	AATCC Test Method 42: Water Penetration ≤ 4.5 g	AATCC Test Method 42: Water Penetration ≤ 4.5 g	*Both meet acceptance criteria*
Synthetic Blood per ASTM F1862	No visible penetration	No visible penetration	*Both meet acceptance criteria*
Fabric Viral Penetration per ASTM F1671	ASTM F1671, Procedure B: no detectable (< 1 PFU/mL)	ASTM F1671, Procedure B: no detectable (< 1 PFU/mL)	*Both meet acceptance criteria*
Particulate Filtration Efficiency per ASTM F2299	≥ 95%	≥ 95%	*Both meet acceptance criteria*
Bacterial Filtration	≥ 95%	≥ 95%	*Both meet acceptance criteria*

Characteristic	Subject Device: Stryker Steri-Shield 8 Surgical Hoods and Togas	Predicate Device: Stryker T7 Surgical Hoods and Togas (K200493)	Equivalence Assessment
Efficiency per ASTM F2101			
Particle Release per ISO 9073-10	Lint Count ≤ 4.0 (Log_{10}, Upper Quartile)	Lint Count ≤ 4.0 (Log_{10}, Upper Quartile)	*Both meet acceptance criteria*
Air Permeability per ASTM D737	Better or equivalent to predicate product	Better or equivalent to predicate product	*Both meet acceptance criteria*
Tear Strength per ASTM D5587	≥ 2.3lbf	≥ 2.3lbf	*Both meet acceptance criteria*
Tensile Strength per ASTM D5034	≥ 7.0lbf	≥ 7.0lbf	*Both meet acceptance criteria*
Seam Strength per ASTM D1683	≥ 7.0lbf	≥ 6.0lbf	*Both meet acceptance criteria*
Evaporative Resistance per ASTM F1868	Better or equivalent to predicate product	Better or equivalent to predicate product	*Both meet acceptance criteria*
Light Transmittance and Haze per ASTM D1003	Better or equivalent to predicate product	Better or equivalent to predicate product	*Both meet acceptance criteria*
Finished (Terminal) Product Sterilization Method	SAL 10^{-6} Terminally sterilized via Ethylene Oxide (EO) in accordance with ISO 11135, Half cycle overkill method	SAL 10^{-6} Terminally sterilized via Ethylene Oxide (EO) in accordance with ISO 11135, Half cycle overkill method	*Identical*
Packaging Configuration	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 specifies part description, quantity, sterilization method, lot	Adhesive backed label placed on carton and pouch label printed directly onto the Tyvek. Label specifies part description, quantity, sterilization method, lot	*Identical*

Characteristic	Subject Device: Stryker Steri-Shield 8 Surgical Hoods and Togas	Predicate Device: Stryker T7 Surgical Hoods and Togas (K200493)	Equivalence Assessment
	number, expiration date, and contact information.	number, expiration date, and contact information.	

Performance Data (Non-Clinical Tests)

The following table provides an overview of the standards and testing conducted in accordance with FDA Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, issued August 1993 and applicable recognized and published standards to aid in determination of the subject devices as safe and effective for use and to support a determination of substantial equivalence.

Testing Standard with Year	Acceptance Criteria	Test Results
Standard for the Flammability of Clothing Textiles (16 CFR Part 1610:2023)	Meets Class 1 requirements	Pass
Water Resistance: Impact Penetration Test (AATCC 42-2017)	Water Penetration ≤ 4.5 grams	Pass
Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) (ASTM F1862/F1862M-2017)	No visible penetration	Pass
Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System (ASTM F1671-2022)	< 1 PFU/mL	Pass
Standard Test Method for Determining the Initial Efficiency of Materials to Penetration by Particulates Using Latex Spheres (ASTM F2299-2017)	≥ 95%	Pass
Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials (ASTM F2101-2022)	≥ 95%	Pass
Textiles. Test methods for nonwovens-Lint and other particles generation in the dry state (ISO 9073-10:2004)	Lint Count ≤ 4.0 (Log_{10}, Upper Quartile)	Pass
Standard Test Method for Air Permeability of Textile Fabrics (ASTM D737-2018)	Better or equivalent to predicate product	Pass

Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure (ASTM D5587-2019)	≥ 2.3lbf	Pass
Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) (ASTM D5034-2021)	≥ 7.0lbf	Pass
Standard Test Method for Failure in Sewn Seams of Woven Fabrics (ASTM D1683/D1683M-17(2018))	≥ 7.0lbf	Pass
Standard Test Method for Thermal Resistance, Evaporative Resistance, and Total Heat Loss Measurements of Clothing Materials Using a Sweating Hot Plate (ASTM F1868-2017)	Better or equivalent to predicate product	Pass
Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics (ASTM D1003-2021)	Better or equivalent to predicate product	Pass
Perforation Tear Strength Testing (Stryker Internal Testing)	0.15lbf < Tear Force ≤ 1.5lbf	Pass

Human Factors and Usability	Product is found to be safe and effective for the intended users, uses and use environment while following Agency "Human Factors and Usability Engineering to Medical Devices" guidance.	Pass
Noise and Speech Interference Levels	Better or equivalent to predicate product	Pass
Carbon Dioxide (CO_2) Testing	Inhale CO2 ≤ 5000ppm per OSHA Exposure Limits	Pass
Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018) • Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity (ISO 10993-5:2009) • Biological evaluation of medical devices – Part 10: Tests for skin sensitization (ISO 10993-10:2021) • Biological evaluation of medical devices – Part 23: Test for irritation (ISO 10993-23:2021) • Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	• Cytotoxicity – MEM Grade ≤ 2 • Sensitization – Sensitization response ≤ 0 • Irritation – Intracutaneous Reactivity ≤ 1.0 • Acute Systemic Toxicity – No signs of toxicity, no weight loss in excess of 10%	Pass*
Biological evaluation of medical devise – Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)	Assessment performed	Comply
Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18: 2020)	Characterization performed	Comply

*Test article Zippered Toga with Peel-Away Face Shield showed a cytotoxic response under the conditions of this test. However, in vivo testing and chemical characterization (extractables and simulated use extractables) were completed and serve to mitigate the in vitro cytotoxicity result observed in the MEM elution assay to support the biocompatibility of the subject article.

Summary of Clinical Testing

No clinical testing was performed for the subject device.

Conclusion/ Substantial Equivalence Rationale

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Stryker Steri-Shield 8 Surgical Hoods and Togas, is as safe, as effective, and performs as well as or better than the legally marketed predicate device under K200493.