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510(k) Summary

K040764

Trade Name:	Stryker T4 Hytrel Zipper Toga
Common Name:	Surgical gown and hood
Classification Name:	Surgical Apparel (per 21 CFR section 878.4040)
Equivalent to:	The Stryker T4 Hytrel Zipper Toga is equivalent to the zipper toga of the Stryker Steri-shield Personal Protection System (K944393, K011755). The material used on the front and sleeves of the Stryker T4 Hytrel Zipper Toga was shown to be equivalent to or better than the material used on the front and sleeves of the Stryker Steri-Shield Personal Protection System (K944393, K011755), as is detailed in Tab 4. Equivalence was based on the results of the following tests: Viral Penetration, Synthetic Blood Pentration, Water Resistance: Impact Penetration, Water Resistance: Hydrostatic Pressure, Flammability, and Tear Resistance
Device Description:	The Stryker Personal Protection Systems include a self-contained ventilation helmet, a hood, a toga, rechargeable battery, and accessories.
Intended Use:	The Stryker T4 Hytrel Zipper Toga is a component of a personal protection system that is intended to provide a barrier between the operating environment and the members of the surgical team in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.
Technological	Technological characteristics are the same as previously cleared for the Stryker Steri-Sheild
Comparison:	Personal Protection System (K944393, K011755).
Submitted by:	Jennifer Mars, Regulatory Affairs Representative Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 Phone- 269-323-7700 ext. 3808 Fax- 269-324-5412
Date Submitted:	March 17, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2004

Stryker Instruments Corporation
Ms. Jennifer Mars
Regulatory Affairs Representative
Instrument Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K040764
Trade/Device Name: The Stryker T4 Personal Protection System: Stryker T4 Hytrel Zipper Toga
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 16, 2004
Received: April 19, 2004

Dear Ms. Mars:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K040764

Device Name The Stryker T4 Personal Protection System: Stryker T4 Hytrel Zipper Toga

Indications For Use The Stryker T4 Hytrel Zipper Toga is a component of a personal protection system that is intended to provide a barrier between the operating environment and the members of the surgical team in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040764