K070078

FEB - 2 2007

4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 800 965 6505
www.stryker.com

stryker

Instruments

510(k) Summary

Device Sponsor: Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001
(p) 269-323-7700
(f) 269-324-5412

Registration No.: 1811755

Trade Name: Stryker T4 Hytrel Toga

Common Name: Surgical gown

Equivalent to: K040764-Stryker Steri-Shield T4 Hytrel Zipper Toga
K011755-Stryker Steri-Shield T4 Hytrel Toga
K944393-Stryker Steri-Shield Protection System

Device Description: The Stryker T4 Hytrel Toga is a single use sterile product that covers the user to minimize potentially hazardous contact between the user and patient.

Intended Use: The Stryker T4 Hytrel 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.

Substantial Equivalence Rational: The Stryker T4 Hytrel Toga is substantially equivalent to **(SE)** devices in commercial distribution. The Stryker T4 Hytrel Togas have the same intended use, similar patient contact materials, same operating principles and physical specifications as compared to predicate devices. There are no new safety or efficacy concerns.

Submitted by: Paulette D. Johnson
Regulatory Affairs Analyst

Date Submitted: 1-23-07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Paulette D. Johnson
Regulatory Affairs Analyst
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001

FEB - 2 2007

Re: K070078
Trade/Device Name: Stryker T4 Hytrel Toga
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA, FXY
Dated: January 3, 2007
Received: January 9, 2007

Dear Ms. Johnson:

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.

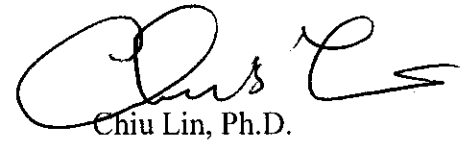
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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

510(k) Number (if known): K070078

Device Name: Stryker T4 Hytrel Toga

Indications for Use: The Stryker T4 Hytrel 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 X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A Murphy MD

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

510(k) Number K070078