K041541



STANDARD TEXTILE

WORLD HEADQUARTERS
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P O BOX 371805
CINCINNATI OHIO
45222-1805
513 761 9255
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## COMPEL MLR™ SURGICAL GOWNS
## SAFETY AND EFFECTIVNESS SUMMARY

MAR 16 2005

The following information is being supplied in accordance with the Safe Medical Device Act of 1990.

807.92(a)

1. Standard Textile Co., Inc.
One Knollcrest Drive
Cincinnati, Ohio 45237
Contact Person: Brad Bushman
(513) 761-9255 Ext.455

2. Device Name: ComPel 3000 Surgical Gowns (Developmental Name)
ComPel MLR Surgical Gowns (Marketing Name)
Common/Usual Name: Non-sterile Surgical Gowns, Operating Room Gowns and Surgical Attire.
Classification Name: Surgical Apparel

3. Predicate Device: ComPel® "O" Surgical Gowns #K921889

4. All fabric components used in ComPel® 3000 Surgical Gowns are made from 100% polyester, solution dyed blue filaments for the outer ComPel 3000 layer and non-dyed filaments with carbon yarns for the inner layer, and are treated with a fluorochemical finish.

   ComPel® 3000 Surgical Gowns will function as a surgical attire when processed according to instructions through 75 complete wash, dry and sterilization cycles. These products will be manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

5. ComPel® 3000 Surgical Gowns are intended to be worn by personnel functioning in the surgical theater and will be put in all critical areas of the product where liquid protection is needed. The liquid barrier properties will inhibit the migration of liquids across its surface. Per ANSI/AAMI PB70:2003, ComPel "3000" surgical gowns with the patented "inverted" 2-ply sleeve designs are classified as a Level 3 Barrier.

6. The tests that have been successfully completed include:
   a. Flammability CFR 1610 (CS-191-53).
   b. Barrier Performance
      i. Suter Hydrostatic Testing AATCC #127-1985
      ii. Impact Penetration Testing AATCC #42-1980
      iii. Water Repellency: Spray Test #22-1980
      iiii. Bacterial Filtration Efficiency - Nelson Laboratories Procedure #SOP/ARO/007C
   c. Strength ASTM D-1682-75
   d. Air Permeability ASTM #737-80
   e. Lint IST 160.0-83
   f. Toxicity - Cytotoxicity MEM Elution (MG023)
   g. Primary Skin Irritation (FHSA)
   h. Sterilization - Product sold non-sterile; can be sterilized using prevacuum or gravity steam cycles.
   i. Durability through 75 processing (wash, dry and sterilization).
   j. Colorfastness to Commercial Laundering - AATCC #61-1993(4A).

To the best of my knowledge, all data and information in the 510(k) are truthful and accurate, and that no material fact has been omitted.

Bradley J. Bushman 6/4/04

Bradley J. Bushman

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Mr. Bradley J. Bushmen
Vice President, Technical Affairs
Standard Textile Company, Incorporated
One Knollcrest Drive
P.O. Box 371805
Cincinnati, Ohio 45222-1805

Re: K041541
Trade/Device Name: ComPel MLR Surgical Gowns
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: February 7, 2005
Received: February 8, 2005

Dear Mr. Bushman:

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.

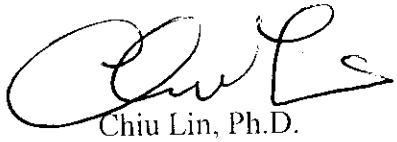
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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): #K041541

Device Name: ComPel MLR Surgical Gowns

Indications For Use:

ComPel MLR Surgical gowns are medical devices that are intended to be worn by operating room personnel during surgical procedures to protect them by inhibiting the migration of liquids through the surface of the critical areas of the gown.

Surgical gowns may provide different levels of protection dependent upon the fabric materials and/or combinations of fabric materials used and the placement of such materials in the final design of the gown.

When processed according to instructions, ComPel MLR Surgical gowns will function and perform as a surgical gown. The ComPel MLR Surgical gowns are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible] of Anesthesiology, General Hospital
[illegible] Control, Dental Devices

[illegible] Number K041541