STANDARD [redacted]
THE HEALTHCARE TEXTILE COMPANY

WORLD HEADQUARTERS
ONE KNOLLCREST DR.
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CINCINNATI, OHIO
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FEB 2 6 1998

K980183

Section VI - 510(k) Summary of Safety and Effectiveness

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
   FDA Registration No. 1527185
   Contact Person: Brad Bushman
   (513)761-9255 Ext. 455
   Summary Prepared on 12-08-97

2. Device Name: ProMax™ Surgical Drapes and Covers

   Common/Usual Name: Non-Sterile Surgical Drapes and Covers

   Classification Name: Drape, Surgical - Fenestrated and Non-Fenestrated

3. Predicate Device: ComPel® Surgical Drapes #K923811

4. ProMax™ Surgical Drapes and Covers can be constructed utilizing one or more types of filament polyester fabrics based on the intended use of the product. The specific fabrics include ProMax™, WrapPel®, ComPel® and Zorwick®.

   ProMax™ Surgical Drapes and Covers will meet performance standards as a surgical drape and cover when processed according to instructions through 75 complete wash, dry and sterilization cycles. These products will be manufactured and distributed as non-sterile surgical drapes and covers that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

5. ProMax™ Surgical Drapes and Covers are intended to be used in health care facilities on patients or surfaces during surgery where protection from liquid migration is needed. The location and level of liquid protection as well as the size and location of a fenestration will vary. The liquid barrier properties will inhibit migration of liquids through its surface.

6. ProMax™ Surgical Drapes and Covers are identical to ComPel® Surgical Drapes and Covers in design, intended use and function, but differ in material. ProMax™ drapes and covers can utilize a vinyl coated polyester knitted fabric (ProMax™ fabric), and ComPel drapes and covers can utilize a silicone coated polyester woven fabric (ComPel XTR®) for areas within the design of these products which require higher levels of liquid resistance.

7. Non-clinical tests demonstrate that the performance of ProMax™ Surgical Drapes and Covers is comparable to ComPel® Surgical Drapes and Covers.

8. The following tests have been successfully completed on ProMax™:

   a. Flammability - Code of Federal Regulations 1610 Standard for the Flammability of Clothing Textiles (CS-191-53) - NFPA 702-1975 (Flammability of Wearing Apparel).
   b. Barrier Performance –
      1) Mullens Hydrostatic Resistance for liquid "proof" fabrics – American Society for Testing & Materials #D-751-79 Method A.
      2) Suter Hydrostatic Resistance for liquid resistant fabrics – American Association for Textile Chemists and Colorists #127-1989.
   c. Colofastness to Commercial Laundering - American Association of Textile Chemist and Colorist #61-1996-4A.
   d. Strength - 1) Tensile Strength for woven fabrics – ASTM #D-1682.
      2) Bursting Strength for knitted and coated fabrics.
   e. Biocompatability - ISO - 10993-1 Biological Evaluation of Medical Devices
      1. Cytotoxicity - NamSA Laboratories - MEM Elution
      2. Primary Skin Irritation - NamSA Laboratories - FHSA
      3. Systemic Toxicity (Saline) - NamSA Laboratories - USP
      4. Systemic Toxicity (Cottonseed Oil) - NamSA Laboratories - USP
      5. Systemic Toxicity (Saline/Alchol) - NamSA Laboratories - USP
      6. Sensitization - NamSA Laboratories - ISO
      7. Hemolysis - NamSA Laboratories - ASTM - MGP72-100

   f. Sterilization - Association for the Advancement of Medical Instrumentation American National Standard - "Guideline for Industrial Moist Heat Sterilization of Medical Products" - ANSI/AAMI ST 25 1987

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 1998

Mr. Bradley J. Bushman
Director, Technical Resources
Standard Textile Company, Incorporated
One Knollcrest Drive
P.O. Box 371805
Cincinnati, Ohio 45222-1805

Re: K980183
Trade Name: ProMax Surgical Drapes and Covers
Regulatory Class: II
Product Code: KKX
Dated: January 12, 1998
Received: January 20, 1998

Dear Mr. Bushman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K980183

DEVICE NAME: ProMax Surgical Drapes and Covers

INDICATIONS FOR USE:

Promax Surgical Drapes and Covers are intended to be used in health care facilities on patients or surfaces during surgical procedures where protection from liquid migration is needed. The liquid barrier will inhibit migration of liquid through its surface.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K980183

Prescription Use _____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109) (Optional Format 1-2-96)