K061242

D.0 510(k) Summary of Safety and Effectiveness

D.1 Submitter Information

JAN 2 5 2007

Company Name and Address:

Precision Fabrics Group, Inc.
301 North Elm Street, Suite 600
Greensboro, NC 27401

Contact Name:

Terry Montgomery, PhD, Vice President
Telephone: (336) 510-8009
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Date Prepared: May 2, 2006

D.2 Name of Device

2.1 Trade Name: Institutional Bedding made with DermaTherapy™ fabrics

2.2 Common Name: DermaTherapy™ bed linens

2.3 Classification Name: Mattress Cover for Medical Purposes (21 CFR 880.6190); Product Code FMW

D.3 Substantial Equivalence Claimed to Predicate Devices

Allergy Control Cover, K903382

D.4 Device Description

The device that is the subject of this 510(k) premarket notification is generally described as Institutional Bedding made with DermaTherapy™ fabrics. Institutional bedding in this case refers to bed linens, generally comprised of a flat top sheet, a fitted or flat bottom sheet, and pillow cases that encase pillows on beds used in hospitals and/or in other healthcare or home settings.

DermaTherapy fabrics are plain-weave constructions of 100% continuous-filament yarns. The preferred embodiment of the technology involves 100% nylon yarns in one direction of the fabric, with 100% polyester yarns in the other direction. The polyester yarns have a non-round fiber cross-section to create micro-channels to facilitate moisture wicking and rapid drying. The yarns used in DermaTherapy fabrics are commercially available products, typically used in women's lingerie or intimate apparel. Once woven, DermaTherapy fabrics are treated with a durable antimicrobial treatment to control bacteria and fungi growth on the fabrics. The antimicrobial treatment applied to DermaTherapy fabrics is a commercially available technology commonly used in the textile industry.

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D.5 **Intended Use**

Institutional Bedding (bed sheets and pillow cases) made with DermaTherapy™ fabrics is intended for use by patients in a hospital, healthcare or home setting who are susceptible to or may have mild atopic dermatitis.

D.6 **Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics**

The comparison of the DermaTherapy™ fabrics was based on a review of the documentation for the device, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate device that was available to the company via public sources, i.e., Allergy Control Cover, K903382. The comparison considered material characteristics and the indications for use / intended use. Neither bench, animal nor clinical testing were assessed.

D.7 **Performance Data**

7.1 Performance Standards (Section 514 Compliance): no applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act, for institutional bedding made with DermaTherapy™ fabrics. Institutional bedding made with DermaTherapy™ fabrics does conform with the FDA recognized standards for biocompatibility.

7.2 Performance Testing: bench testing was performed and all tests showed satisfactory results. A clinical study was performed and included 37 subjects with mild atopic dermatitis. Results showed statistically significant improvements in the severity of atopic dermatitis, eczema, the level of itching, and perceived quality of life after eight weeks of using DermaTherapy bedding.

D.8 **Conclusion**:

The information and data provided in this 510(k) Premarket Notification establish that Institutional Bedding (bed sheets and pillow cases) made with DermaTherapy™ fabrics is substantially equivalent to the afore-mentioned predicate device with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terry Montgomery, Ph.D.
Vice President
Precision Fabrics Group, Incorporated
301 North Elm Street, Suite 600
Greensboro, North Carolina 27401

JAN 25 2007

Re: K061242
Trade/Device Name: Institutional Bedding made with DermaTherapy™ Fabrics
Regulation Number: 880.6190
Regulation Name: Mattress Cover for Medical Purposes
Regulatory Class: I
Product Code: FMW
Dated: January 5, 2007
Received: January 8, 2007

Dear Dr. Montgomery:

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

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Section 4.0 - Indications for Use Statement

4.0 ODE Indications Statement

510(k) Number (if known): ***Unknown***

Device Name: Institutional Bedding made with DermaTherapy™ Fabrics

Indications for Use: Institutional Bedding (bed sheets and pillow cases) made with DermaTherapy™ fabrics is intended for use by patients in a hospital, healthcare or home setting who are susceptible to or may have mild atopic dermatitis.

Prescription Use: ☐	AND/OR	Over-the-Counter Use: ☒
(Part 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)

[illegible]

[illegible] General Hospital,

[illegible]

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