DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 20, 2016

Precision Fabrics Group, Inc.
% Mr. Jonathan Kahan
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20004

Re: K152884
Trade/Device Name: DermaTherapy Bed Linens
Regulation Number: 21 CFR 880.6190
Regulation Name: Mattress Cover for Medical Purposes
Regulatory Class: I
Product Code: FMW
Dated: May 20, 2016
Received: May 20, 2016

Dear Mr. Kahan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K152884

Device Name

DermaTherapy Bed Linens

Indications for Use *(Describe)*

Bed linens made with DermaTherapy® fabrics are intended for use by patients 18 years of age and older in hospital settings who are susceptible to pressure ulcers. The DermaTherapy Bed Linens help to reduce the likelihood of patients developing pressure ulcers by reducing moisture, friction and shear on the patient's skin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K152884

Precision Fabrics Group's DermaTherapy Bed Linens

Submitter Information:

Applicant:	Precision Fabrics Group, Inc. 301 North Elm Street, Suite 600 Greensboro, NC 27401
Phone:	(336) 510-8009
Fax:	(336) 510-8003
Contact Person:	Terry Montgomery, PhD, Vice President
Date Prepared:	June 15, 2016

Subject Device:

Device Name:	DermaTherapy Bed Linens
Common Name:	Bed linens
Classification Name:	Mattress Cover for Medical Purposes
Regulation:	Class I, 21 C.F.R. § 880.6190
Product Code:	FMW

Predicate Devices:

Primary Predicate:	Precision Fabrics Group's Institutional Bedding made with DermaTherapy Fabrics (K061242)

Indications for Use:

Bed linens made with DermaTherapy fabrics are intended for use by patients 18 years of age and older in hospital settings who are susceptible to pressure ulcers. The DermaTherapy Bed Linens help to reduce the likelihood of patients developing pressure ulcers by reducing moisture, friction and shear on the patient's skin.

Device Description

DermaTherapy uses a silk-like fabric to minimize moisture, friction, and shear between the skin and the bed-support surface. Continuous-filament yarns woven into the silk-like synthetic DermaTherapy fabric provide a smooth surface, free of broken or discontinuous fibers. This enhanced smoothness helps minimize the potential for irritation and abrasion of sensitive skin.

DermaTherapy Bed Linens consists of pillow cases, top flat sheets, bottom fitted sheets, and underpads. The subject devices are made from DermaTherapy fabrics which are plain-weave constructions of 100% continuous-filament yarns. 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 apparel.

The only technological difference in the fabric construction between the subject device and the predicate device is the addition of a secondary static-dissipative polyester yarn at 0.8% of the total fabric weight. The static-dissipative yarn is incorporated to reduce the potential for static electricity that may occur during institutional laundering processes. The company has made no other modifications to the fabric or the manufacturing process of turning the fabric into the final product.

Substantial Equivalence

The DermaTherapy Bed Linens are substantially equivalent to the primary predicate device, Institutional Bedding made with DermaTherapy Fabrics (K061242). Both devices have the same intended use as mattress covers that protect the skin, and similar technological characteristics. The new indications for use do not raise new questions of safety and effectiveness. The additional static-dissipative yarn does not affect the intended use or the device performance. Furthermore, bench testing demonstrated that the device met performance specifications, which support the new indications for use. Thus, the subject device is substantially equivalent to the primary predicate devices.

A summary of substantial equivalence between the subject, primary predicate, and reference devices are provided in Table 1 below.

Table 1: Substantial Equivalence Comparison

	Subject Device: **DermaTherapy Bed Linens**	**Primary Predicate Device:** **Institutional Bedding made with DermaTherapy fabrics (K061242)**
Indications for Use	Bed linens made with DermaTherapy® fabrics are intended for use by patients 18 years of age and older in hospital settings who are susceptible to pressure ulcers. The DermaTherapy Bed Linens help to reduce the likelihood of patients developing pressure ulcers by reducing moisture, friction and shear on the patient's skin.	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.
User Population	Patients in hospital settings	Patients in hospital and long-term care settings

	Subject Device: **DermaTherapy Bed Linens**	**Primary Predicate Device:** **Institutional Bedding made with DermaTherapy fabrics (K061242)**
Classification	Mattress Cover for Medical Purposes Class I 21 CFR 880.6190 Product Code FMW	Mattress Cover for Medical Purposes Class I 21 CFR 880.6190 Product Code FMW
Technological Characteristics	DermaTherapy fabrics made of nylon, polyester, and static-dissipating yarn with antimicrobial treatment	DermaTherapy fabrics made of nylon and polyester yarn with antimicrobial treatment
Features	Bed linens designed to reduce moisture, friction and shear on the patient's skin. Fabric is undyed in natural white color.	Bed linens designed to reduce moisture, friction and shear on the patient's skin. Fabric is undyed in natural white color.
Components	Pillow cases, top flat sheets, bottom fitted sheets, and underpads Antimicrobial agent: quaternary ammonium compound (3-Trimethoxy silyl propyl dimethyl octadecyl ammonium chloride), is applied to the DermaTherapy fabric	Pillow cases, top flat sheets, and bottom fitted sheets Antimicrobial agent: quaternary ammonium compound (3-Trimethoxy silyl propyl dimethyl octadecyl ammonium chloride), is applied to the DermaTherapy fabric
Dimensions	Pillow Case at 21" width x 32" length (Standard). Top Flat Sheet at 70" width x 108" length (XL Twin). Bottom Fitted Sheet at 39" width x 81" length x 15" height (XL Twin). Underpad at 32" width x 30" length.	Pillow Case at 21" width x 32" length (Standard). Top Flat Sheet at 70" width x 108" length (XL Twin). Bottom Fitted Sheet at 39" width x 81" length x 15" height (XL Twin).
Biocompatibility	Cytotoxicity, sensitization, and irritation testing	Cytotoxicity, sensitization, and irritation testing
Sterilization	Not sterile	Not sterile

Performance Data

Extensive bench testing has been performed to various standards, both industry- and company-specific, to ensure that the device meets the device performance specifications at the beginning and at the end of its use life. A summary of the testing conducted is provided in Table 2 below:

Table 2: Performance Characteristics and Test Methodology

Performance Characteristics	**Test Method / Standard**
Weave Pattern	Visual
Weight	ASTM-D-3776
Ends	ASTM-D-3775
Picks	ASTM-D-3775
Grab Tensile – Warp & Fill	ASTM-D-5034
Tongue Tear – Warp & Fill	ASTM-D-2261
Circular Bend	ASTM-D-4032
Pore Size	ASTM-E-1294
Moisture Regain	ASTM-D-2654

Performance Characteristics	Test Method / Standard
Geometric Roughness	The surface contour (geometric roughness) is determined using the Kawabata KES-FB4 Surface Tester. Measurements are made using a standard specimen size of 20 x 20 cm in three replications. Using a calibrated surface probe, geometric roughness is measured in microns. Higher values correspond to a geometrically rougher surface.
Fabric Wicking Rate – Warp & Fill	A determination of the rate at which a fabric wicks water, measured as the distance water travels in five minutes. A 1" x 6" sample is marked and lowered into deionized water. The wicking rate is calculated by determining the distance, measured in millimeters, water rises along the sample fabric in a 5-minute period.
% Dry after 0 - 60 minutes	A determination of % moisture loss of a fabric until dryness, measured in 15-minute intervals up to 60 minutes, whichever comes first. An 8"x10" fabric sample is tested at intervals. The rate is calculated based upon the time it takes for the sample to return to its original dry weight.
Coefficient of Friction	The surface properties of friction (resistance/drag) are determined using the Kawabata KES-FB4 Surface Tester. Measurements are made using a standard specimen size of 20 x 20 cm in three replications. Using a calibrated friction probe, coefficient of friction (COF) values of 0 to 1 are determined, with the higher COF value corresponding to higher friction.

Cytotoxicity, intracutaneous reactivity, and skin sensitization testing were conducted according to ISO 10993 consensus standards to evaluate the biocompatibility of the device at various points of its use life.

PFG conducted a leachability study to quantify and to analyze the antimicrobial agent leaching from the subject device and the predicate device. Test results demonstrated that the subject device exhibited substantially equivalent amount of antimicrobial agent leaching from the device. In addition, a risk assessment of the antimicrobial agent completely leaching from the product demonstrated that there is no safety risk to the patient.

Clinical Data

To further demonstrate the substantial equivalence and performance of the device in reducing the likelihood of patients developing pressure ulcers, the company has conducted three studies since 2008 that included a total of 2,009 study subjects. A summary of the studies is provided in Table 3 below. Study subjects included patients 18 years of age and older in acute care setting at multiple healthcare sites including medical renal, urology, surgical intensive care, non-surgical intensive care, and telemetry units. Comparison of data between the study and control groups showed a consistent reduction in the incidence of facility-acquired pressure ulcers in a wide range of clinical settings and patient populations. No product-related adverse events or complications were reported over the entire study period.

Table 3: Incidence of Facility-Acquired Pressure Ulcers

Study	Clinical Trials	Total Patients	Control	DermaTherapy	*P*
1.	Acute Care: Medical Renal Unit	307	12.3%	4.6%	.01
2.	Acute Care: Surgical ICU	275	7.5%	0.0%	.01
3.	Acute Care: Telemetry/Urology/ICU	1,427	11.5%	3.1%	<.001

Conclusions

Precision Fabrics Group believes that DermaTherapy Bed Linens are substantially equivalent to the primary predicate device Institutional Bedding made with DermaTherapy fabrics (K061242). Both devices have the same intended use and similar indications for use. The only difference to the predicate device is the addition of static-dissipative polyester yarn. Bench testing has demonstrated substantially equivalent device performance and supports the expanded indications for use to reduce the formation of pressure ulcers. Therefore, the subject device is substantially equivalent to the primary predicate device.