May 18, 2018

Vestagen Protective Technologies, Inc.
Scott Pease
Sr. Vice President of Regulatory and Quality
1301 W. Colonial Dr.
Orlando, Florida 32804

Re: K180217
Trade/Device Name: VESTEX Apparel ("VESTEX")
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QBW
Dated: April 16, 2018
Received: April 17, 2018

Dear Scott Pease:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180217

Device Name
VESTEX® Apparel ("VESTEX")

Indications for Use *(Describe)*
VESTEX® Apparel ("VESTEX"), scrub tops, pants, skirts, and lab coats are apparel that provides fluid repellency and reduces the retention of Methicillin Resistant Staphylococcus aureus (MRSA) on the surface (outer layer) of the apparel.

The ability of VESTEX to reduce the retention of MRSA on the fabric surface has not been shown to correlate with the reduction of infections. Clinical studies to evaluate reduction in infection have not been performed for this device.

VESTEX Apparel is not intended to replace personal protective equipment.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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VESTEX® Apparel "Vestex"

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Vestagen Protective Technologies, Inc.
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Contact Person: Scott Pease, Sr. Vice President of Regulatory and Quality (scott.pease@vestagen.com)

Date Prepared: May 3, 2018

Name of Device	VESTEX® Apparel
Common or Usual Name	Healthcare Practitioner Apparel (Scrub)
Classification Name	Suit, Surgical
Product Code / Regulation Classification	QBW / 21 CFR § 878.4040 Class II
Predicate Devices	K891212 (Aprons, Scrub Slacks & Tops, Patient Drape) – Pro-Safe Professional Linens, Inc.

Indications for Use

VESTEX® Apparel ("VESTEX"), scrub tops, pants, skirts, and lab coats are apparel that provides fluid repellency and reduces the retention of Methicillin Resistant Staphylococcus aureus (MRSA) on the surface (outer layer) of the apparel.

The ability of VESTEX to reduce the retention of MRSA on the fabric surface has not been shown to correlate with the reduction of infections. Clinical studies to evaluate reduction in infection have not been performed for this device.

VESTEX Apparel is not intended to replace personal protective equipment.

Device Description / Technological Characteristics

VESTEX® Apparel is nonsterile, reusable, fluid repellant apparel containing an antimicrobial agent that is designed for continuous wear to provide protection to healthcare workers where intermittent or unexpected exposure to microorganisms from blood, body fluids and other potentially infectious material (OPIM) can occur.

VESTEX® does not replace PPE worn for specific use and during episodes of expected blood, body fluid and other potentially infectious material (OPIM) exposure.

VESTEX® has a dual mechanism of action that is fluid repellant and an antimicrobial agent. VESTEX® has a proprietary application method used to covalently bond a fluid repellent and an antimicrobial agent to the outer surface of the fabric.

The primary mechanism of action is a fluid repellant fabric surface which acts to resist bacteria acquisition on the fabric. As the fluids and pathogens are repelled, the numbers of microorganisms that remain on the fabric are significantly reduced.

The secondary mechanism of action is an antimicrobial agent. It has one of several possible modes of action, including disruption of the cell membrane, denaturation of cell surface and transmembrane proteins, and inactivation of bio-energetic systems to prevent the microorganisms from being retained on the fabric. This secondary mechanism of action reduces Methicillin Resistant Staphylococcus aureus (MRSA) on the surface (outer layer) of the apparel.

Performance Data

Biocompatibility and functional bench testing performed by Vestagen Protective Technologies, Inc. demonstrates VESTEX® Apparel substantial equivalence, in terms of the safety and effectiveness, to the referenced predicate device. In vitro bench testing included an assessment of all design input requirements and confirmation that the output of the design process met all design input requirements was completed, including those relating to appropriate standards and guidance's, as follows:

Biocompatibility

- ISO 10993-1:2009 – Biological Evaluation of Medical Devices- Part I: Evaluation and Testing
    - Skin Sensitization
    - Irritation
    - Cytotoxicity

Functional

- ASTM D1424-09:2013 – Tearing Strength of Fabrics by Falling-Pendulum (Elemdorf-Type) Apparatus
- Fabric Clinical Environment / Reuse
    - Pre-Conditioning
    - Fluid Repellency: Spray Test
    - Splatter Testing (Reduction of MRSA Retention)
    - Cleaning Validation

Additionally, in a randomized, blinded, crossover trial within a medical ICU, VESTEX® apparel demonstrated its effectiveness in reducing accumulation of Methicillin Resistant Staphylococcus aureus (MRSA) on health care workers (HCW) clothing[1)] compared to control clothing. The MRSA reduction as statically significant both at the beginning and end of a 12 hour work shift.

[1)] *Bearman, GML, et al. A Crossover Trial of Antimicrobial Scrubs to Reduce Methicillin-Resistant Staphylococcus aureus Burden on Healthcare Worker Apparel. Infection Control and Hospital Epidemiology. Vol. 33, No. 3 (March 2012), pp. 268-275.*

Summary of Substantial Equivalence

Feature	Subject Device (K180217)	Predicate Device (K891212)
Intended Use / Indications	VESTEX® Apparel ("VESTEX"), scrub tops, pants, skirts, and lab coats are apparel that provides fluid repellency and reduces the retention of Methicillin Resistant Staphylococcus aureus (MRSA) on the surface (outer layer) of the apparel. The ability of VESTEX to reduce the retention of MRSA on the fabric surface has not been shown to correlate with the reduction of infections. Clinical studies to evaluate reduction in infection have not been performed for this device. VESTEX Apparel is not intended to replace personal protective equipment.	Protective apparel for dentists to prevent the migration of bacteria and liquids.
Materials of Construction	79% Polyester, 18% Rayon, 3% Spandex	65% polyester, 35% cotton back with Barrier Supreme® 50% cotton 50% polyester front.
Design Features	One layer of fabric constructed as an active barrier. Exterior has a dual mechanism of action to include a fluid barrier and antimicrobial agent. Interior has moisture wicking on the skin touching side of the fabric.	One layer of fabric Scrub Top and Slacks constructed with a fluid resistant fabric in front of the garment.
Performance Testing	Biocompatibility: Yes – ISO 10993-1 Fluid Repellency (@ 0 & 50 washes): Yes – Simulated Worst Case Study (Variation of AATCC22) Durability & Tear Strength: Yes – ASTM D1424 Splatter Challenge (Reduction of MRSA Retention @ 0 & 50 Washes): Yes – Simulated Worst Case Study Clinical Trial Yes – Bearman, GML, et al. A Crossover Trial of Antimicrobial Scrubs to Reduce Methicillin-Resistant Staphylococcus aureus Burden on Healthcare Worker Apparel	Biocompatibility: Not available Fluid Repellency (@ 0 & 50 washes): Yes – AATCC22 Durability & Tear Strength: Yes – ASTM D2261 Reduction of MSRA Retention: No Clinical Trial No

Based upon the device description, technical characteristics and test data provided within this submission, VESTEX® Apparel is substantially equivalent to the referenced predicate devices.