October 11, 2019

Global Health Solutions (DBA Turn Therapeutics)
Bradley Burnam
Official Correspondent
2362 Calabasas Road #100
Calabasas, California 91302

Re: K183681
Trade/Device Name: Protego Antimicrobial Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 10, 2019
Received: September 12, 2019

Dear Bradley Burnam:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Cynthia J. Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K183681

Device Name
Protego Antimicrobial Wound Dressing

Indications for Use *(Describe)*
Under the management of a healthcare professional, Protego Antimicrobial Wound Dressing is intended for the management of first and second degree burns, venous stasis ulcers, diabetic ulcers, partial and full thickness wounds, donor sites, post-surgical incisions, trauma wounds, and abrasions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary

1. **Submission Sponsor**:

Global Health Solutions (DBA Turn Therapeutics)
23632 Calabasas Road, #100
Calabasas, CA 91302

2. **Submission Contact**:

Bradley Burnam
Phone: 818-312-6621
Email: brad@turntherapeutics.com

3. **Date Prepared:** September 2, 2019

4. **Device Identification:**

Trade Name: Protego Antimicrobial Wound Dressing
Common Name: Wound Dressing
Classification Name: Dressing, Wound, Drug
Product Code: FRO
Device Class: Unclassified

5. **Predicate Devices:**

PolyPlex Wound Dressing (K160872)

6. **Description of Proposed Device:**

Protego Antimicrobial Wound Dressing is a sterile, single-use, non-adherent gauze dressing impregnated with an odorless petrolatum-based emulsion. The impregnated gauze is placed in a sealed pouch. The product contains Polyhexamethylene Biguanide (PHMB) and Benzalkonium Chloride (BZK) to prevent microbial colonization within the dressing. Protego Antimicrobial Wound Dressing is intended to maintain a moist environment that is conducive to healing. Protego Antimicrobial Wound Dressing is packaged in single-use, LDPE tear pouches. Protego Antimicrobial Wound Dressing comes in three sizes, including 4"x 4," 1"x 8," and 2"x 2," with no difference in materials among the different sizes.

7. **Indications for Use Statement:**

Under the management of a healthcare professional, Protego Antimicrobial Wound Dressing is intended for the management of first and second degree burns, venous stasis ulcers, diabetic ulcers, partial and full thickness wounds, donor sites, post-surgical incisions, trauma wounds, and abrasions.

8. **Performance Testing:**

Results of in vitro testing indicate that Protego Antimicrobial Wound Dressing effectively inhibits the growth of microorganisms within the dressing for up to 24 hours. The product is non-cytotoxic, non-sensitizing, and non-irritating per ISO 10993 biocompatibility trials.

9. Substantial Equivalence Discussion:

It has been shown that the technological/formulaic differences between Protego Antimicrobial Wound Dressing and the predicate device do not raise concerns regarding the safety and/or efficacy of the proposed product. The product is substantially equivalent to the predicate device.

Device	PolyPlex Wound Dressing	Protego Antimicrobial Wound Dressing
510(k)	K160872	K183681
Pro code	FRO	FRO
Manufacturer	Global Health Solutions	Turn Therapeutics
Indications	Under the management of a healthcare professional, PolyPlex Wound Dressing is intended for the management of first and second degree burns, venous stasis ulcers, diabetic ulcers, partial and full thickness wounds, donor sites, post-surgical incisions, trauma wounds, and abrasions. It can be used during wound dressings changes to soften encrusted wound dressings.	Under the management of a healthcare professional, Protego Antimicrobial Wound Dressing is intended for the management of first and second degree burns, venous stasis ulcers, diabetic ulcers, partial and full thickness wounds, donor sites, post-surgical incisions, trauma wounds, and abrasions.
Sterility	Non-Sterile	Sterile
Prescription	Prescription	Prescription
Ingredients	Petrolatum, water, PHMB, BZK	Petrolatum, water, PHMB, BZK, non-woven
Use Duration	72h	24h
Shelf Life	No shelf life	No shelf life
Comparison		sterilized by gamma irradiation, pouch containing nonwoven gauze impregnated with petrolatum-based emulsion