April 29, 2020

Gunze Limited
% Stuart Goldman
Senior Consult
Emergo Global Consulting , LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K191992
Trade/Device Name: PELNAC Bilayer Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 24, 2020
Received: March 26, 2020

Dear Stuart Goldman:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
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)*
K191992

Device Name
PELNAC™ Bilayer Wound Matrix

Indications for Use *(Describe)*
PELNAC™ Bilayer Wound Matrix is indicated for the management of wounds including:

- partial and full-thickness wounds,
- pressure ulcers,
- venous ulcers,
- diabetic ulcers,
- chronic vascular ulcers,
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and
- draining wounds.

The device is intended for one-time use.

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.

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510(k) Summary

PELNAC™ Bilayer Wound Matrix

1. Submission Sponsor

GUNZE LIMITED
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2. Submission Correspondent

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Contact: Stuart R. Goldman
Title: Sr. Consultant RA/QA

3. Date Prepared

April 29, 2020

4. Device Identification

Trade/Proprietary Name: PELNAC™ Bilayer Wound Matrix
Common/Usual Name: Wound Dressing
Classification Name: Dressing, Wound, Collagen
Regulation Number: Pre-Amendment Device
Product Code: KGN
Class: Unclassified (Pre-Amendment Device)
Review Panel: General & Plastic Surgery

5. Legally Marketed Predicate and Reference Devices

- Predicate Device (AVAGEN):
    - Integra Life Sciences Corp. – AVAGEN Wound Dressing (K022127 / KGN)

The predicate device has not been subject to a design related recall.

- Reference Device #1 (BMWD):
    - Integra Life Sciences Corp. – Bilayer Matrix Wound Dressing (K021792 / FRO)
- Reference Device #2 (IMBWM):
    - Integra Life Sciences Corp. – INTEGRA™ Meshed Bilayer Wound Matrix (K081635 / FRO)
- Reference Device #3 (WMTF):
    - Miromatrix Medical, Inc. – Wound Matrix TF (K143426 / KGN)

6. Indications for Use

PELNAC™ Bilayer Wound Matrix is indicated for the management of wounds including:

- partial and full-thickness wounds,
- pressure ulcers,
- venous ulcers,
- diabetic ulcers,
- chronic vascular ulcers,
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and
- draining wounds.

The device is intended for one-time use.

7. Device Description

PELNAC™ Bilayer Wound Matrix is a collagen-based wound matrix that consists of two layers: a porcine collagen sponge layer and a silicone film layer and is offered in two versions: 1. Meshed Type (i.e., fenestrated) and 2. Non-Meshed Type (i.e., non-fenestrated). The collagen sponge layer should be applied to the wound surface. Both versions of the device also contain a synthetic gauze material to add strength to the silicone film layer. When applied to full-thickness skin defects, PELNAC™ Bilayer Wound Matrix provides a scaffold for cellular invasion and capillary growth. PELNAC™ Bilayer Wound Matrix is offered in sheet form of various sizes and is provided terminally sterilized by ethylene oxide, is for single patient use, and can only be applied to a patient by a qualified doctor in a professional setting for the management of full-thickness skin defects as described in its product labeling.

8. Substantial Equivalence Discussion

PELNAC™ Bilayer Wound Matrix has the same indications for use as the predicate device AVAGEN Wound Dressing (K022127), except for those indications related to tunneled / undermined wounds found in the predicate device which are not included in the indications for the subject device. The subject and predicate devices employ the same mode of action in that both devices contain a porous sponge-like matrix of animal-derived collagen that serves as a scaffold for cellular invasion and capillary growth.

Table 5-1 compares PELNAC™ Bilayer Wound Matrix to the predicate device AVAGEN (K022127) with respect to regulatory information, intended use, indications for use, technological characteristics, and safety and

performance testing and provides detailed information regarding the basis for the determination of substantial equivalence between the subject and predicate device. Similar and relevant information on the reference devices is also included in **Table 5-1**.

Table 5-1 – Substantial Equivalence Comparison of PELNAC™ Bilayer Wound Matrix vs. Predicate and Reference Devices

Attributes	Subject Device	Predicate Device (AVAGEN)	Reference Device #1 (BMWD)	Reference Device #2 (IMBWM)	Reference Device #3 (WMTF)	Similarities / Differences
Regulatory Information						
Device Name	PELNAC™ Bilayer Wound Matrix (Non-Meshed Type and Meshed Type)	AVAGEN Wound Dressing	Bilayer Matrix Wound Dressing	Integra Meshed Bilayer Wound Matrix	Wound Matrix TF	-
Manufacturer	GUNZE LIMITED	Integra Life Sciences	Integra Life Sciences	Integra Life Sciences	Miromatrix Medical	-
510(k) #	Pending	K022127	K021792	K081635	K143426	-
Product Code	KGN	KGN	FRO	FRO	KGN	Same for the subject and predicate device.
Regulation	Pre-Amendment	Pre-Amendment	Pre-Amendment	Pre-Amendment	Pre-Amendment	Same for the subject and predicate device.
Class	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified	Same for the subject and predicate device.
Review Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same for the subject and predicate device.

Indications for Use	PELNAC™ Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds. The device is intended for one-time use.	AVAGEN Wound Dressing is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is intended for one-time use.	Bilayer Matrix Wound Dressing is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is intended for one-time use.	INTEGRA™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and draining wounds. May be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.	Wound Matrix TF is intended for the management of wounds including: Partial and full thickness wounds; Pressure ulcers; Venous ulcers; Diabetic ulcers; Chronic vascular ulcers; Tunneled, undermined wounds; Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence); Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears); Draining wounds. The device is supplied sterile and is intended for one-time use.	Same. Except for those indications related to *tunneled /undermined wounds* found in the predicate device which are not found in the subject device, the subject and predicate device have the same indications for use.

Attributes	Subject Device	Predicate Device (AVAGEN)	Reference Device #1 (BMWD)	Reference Device #2 (IMBWM)	Reference Device #3 (WMTF)	Similarities / Differences
Technological Characteristics						
Construction	Bilayer	Single layer	Bilayer	Bilayer	Single layer	Different. Therefore, Reference Devices 1/2 were added to the substantial equivalence discussion.
Form	Sheet	Sheet	Sheet	Sheet	Sheet	Same
Materials	Silicone film, synthetic gauze, and collagen sponge porous matrix of porcine (Achilles) tendon.	Collagen sponge porous matrix of bovine tendon + glycosaminoglyca.	Silicone film and collagen sponge porous matrix of bovine tendon + glycosaminoglyca.	Silicone film and collagen sponge porous matrix of bovine tendon + glycosaminoglyca.	Porous matrix of porcine derived (liver tissue) collagen matrix.	Different. Therefore, Reference Device 3 was added to the substantial equivalence discussion.
Meshed (fenestrated) Structure	No / Yes	No	No	Yes	No	Different. Therefore, Reference Devices 2/3 were added to the substantial equivalence discussion.
Mode of Action	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth.	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth.	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth.	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth.	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth.	Same

Attributes	Subject Device	Predicate Device (AVAGEN)	Reference Device #1 (BMWD)	Reference Device #2 (IMBWM)	Reference Device #3 (WMTF)	Similarities / Differences
Single Use	Yes	Yes	Yes	Yes	Yes	Same
Supplied Sterile	Yes (EO)	Yes (radiation)	Yes (radiation)	Yes (radiation)	Yes (radiation)	Same
Shelf Life	36 months	24 months	24 months	24 months	-	Similar
Sizes	20 × 30 mm 40 × 30 mm 40 × 60 mm 82 × 60 mm 82 × 90 mm 82 × 120 mm 120 × 240 mm 200 × 240 mm	100 × 125 mm 100 × 250 mm 200 × 250 mm	50 × 50 mm 100 × 125 mm 100 × 250 mm 200 × 250 mm	50 × 50 mm 100 × 125 mm 100 × 250 mm 200 × 250 mm	20 × 20 mm 20 × 30 mm 30 × 30 mm 30 × 70 mm 40 × 40 mm 50 × 50 mm 80 × 80 mm 70 × 100 mm 80 × 150 mm	Similar. The sizes of the subject device fall within the size range of the predicate device and Reference Device 3.
Safety and Performance Testing						
Biological Evaluation	ISO 10993-1: - Cytotoxicity, - Skin Sensitization, - Intracutaneous Reactivity, - Implantation, - Material-mediated Pyrogenicity, - Chemical Characterization, - Toxicological Risk Assessment	ISO 10993-1: - Cytotoxicity, - Dermal Sensitization, - Irritation, - Acute Systemic Toxicity, - Hemolysis, - Pyrogenicity	ISO 10993-1: - Cytotoxicity, - Dermal Sensitization, - Irritation, - Acute Systemic Toxicity, - Hemolysis, - Pyrogenicity	ISO 10993-1: - Cytotoxicity, - Dermal Sensitization, - Irritation, - Acute Systemic Toxicity, - Hemolysis, - Pyrogenicity	ISO 10993-1: - Cytotoxicity, - Skin Sensitization, - Intracutaneous Reactivity, - Acute Systemic Toxicity, - In Vitro Bacterial Reverse Mutation, - In Vitro Chromosome Aberration, - In Vitro Mammalian Cell Gene Mutation, - Pyrogenicity,	Similar

Attributes	Subject Device	Predicate Device (AVAGEN)	Reference Device #1 (BMWD)	Reference Device #2 (IMBWM)	Reference Device #3 (WMTF)	Similarities / Differences
					- Sub-Chronic Systemic Toxicity	
Collagen Viral Inactivation	Performed	Performed	Performed	Performed	Performed	Similar
Physical and Chemical Properties Testing	Performed	Performed	Performed	Performed	Performed	Similar
Non-Clinical Performance Testing	Performed	Unknown	Performed	Performed	Performed	Similar

9. Summary of Safety and Performance Testing

As part of demonstrating substantial equivalence of the subject device to the predicate device, GUNZE LIMITED tested final finished samples of PELNAC™ Bilayer Wound Matrix for testing in accordance with the applicable parts of the following FDA guidance documents, voluntary FDA recognized consensus and other standards and to internal GUNZE test protocols and procedures referenced below. Results confirm that the design inputs and performance specifications for the subject device have been met.

- Animal Tissue Sourcing and Viral Inactivation:
  - FDA Guidance Document – *Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)* - 2019
  - FDA Guidance Document – *Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin* - 1998
- Biocompatibility:
  - FDA Guidance Document – *Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process*
  - ISO 10993-1:
    - ISO 10993-5 (cytotoxicity)
    - ISO 10993-6 (implantation)
    - ISO 10993-10 (skin sensitization and intracutaneous reactivity)
    - ISO 10993-11 (systemic toxicity)
    - ISO 10993-17 (toxicological risk assessment)
    - ISO 10993-18 (chemical characterization)
- Sterilization, Packaging and Shelf Life:
  - ISO 11135
  - ISO 11607-1
  - ASTM F1886
  - USP <85> Bacterial Endotoxin Test
- Usability:
  - IEC 62366-1
- Risk Analysis:
  - ISO 14971
- Physical and Chemical Properties Testing
- Non-Clinical Performance Testing

10. Summary of Clinical Data

To address the subject product immunogenicity, a Human Repeat Insult Patch Test (HRIPT) was conducted on 56 subjects. PELNAC Bilayer Wound Matrix was placed on the subjects 9 (nine) times during the induction phase and the area was evaluated at each visit prior to the next patch placement. After 2-3 weeks rest period the subjects were challenged by placing the device at the same area and evaluated at 24, 48, 72 & 96 hours for irritation and Type IV allergic response. The results demonstrated that none of the 56 subjects developed irritation or sensitization. There were no adverse events related to the product demonstrating that PELNAC Bilayer Wound Matrix is neither an irritant nor a sensitizer.

In lieu of the prick test to demonstrate that the subject device does not elicit immunogenic reaction (antibody-mediated) and does not cause any local inflammatory tissue responses, PELNAC Bilayer Wound Matrix was used on a cohort of 18 subjects who sustained finger degloving injuries. The subjects ranged in age from 19 to 66 years, mean age 42 years. They received the subject device within 2 days of their injury, and it remained in place for 21 days. The patients remained in the hospital for at least 24 hours after the surgery in which the subject device was placed and then were evaluated weekly until day 21. There were no reports of expanding erythema, edema, pain, vesicles, or other immune response that would signal removal of the dressing. All subjects were followed at 3, 6, 9, and 12 months. Assessments were evaluated at the 12 month follow up including biopsy samples and histological analysis.

11. Statement of Substantial Equivalence

PELNAC™ Bilayer Wound Matrix has the same intended use and indications for use as AVAGEN Wound Dressing. Any minor differences in the technological features of the subject device when compared to the predicate device have been successfully evaluated through safety and performance testing and other verification and validation activities. PELNAC™ Bilayer Wound Matrix, as designed and manufactured by GUNZE LIMITED has been determined to be substantially equivalent to the predicate device, AVAGEN Wound Dressing.