July 14, 2022

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

Re: K213498
Trade/Device Name: PELNAC® Meshed Bilayer Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 1, 2022
Received: June 7, 2022

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,

Julie Morabito, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213498

Device Name
PELNAC® Meshed Bilayer Wound Matrix

Indications for Use *(Describe)*
PELNAC® 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, partial thickness burns, and skin tears), and
- draining wounds.

The device may be used in conjunction with negative pressure wound therapy. 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® Meshed Bilayer Wound Matrix
K213498

1. Submission Sponsor

GUNZE LIMITED
Medical Division
46 Natsumegaichi, Aono
Ayabe, Kyoto
Japan 623-8513
Contact: Mr. Hidenori Nishioka
Title: Regulatory Affairs

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Contact: Mr. Stuart R. Goldman
Title: Sr. Consultant RA/QA

3. Date Prepared

July 12, 2022

4. Device Identification

Type of 510(k):	Traditional 510(k)
Trade Name:	PELNAC® Meshed Bilayer Wound Matrix
Product Code:	KGN
Classification Name:	Dressing, Wound, Collagen
Regulation Number:	Pre-Amendment
Regulation Description:	Pre-Amendment
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device

Trade Name:	INTEGRA™ Meshed Bilayer Wound Matrix
510(k) No.:	K081635
Manufacturer:	Integra Life Sciences

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

The following reference device is also included in this submission.

Trade Name:	PELNAC™ Bilayer Wound Matrix
510(k) No.:	K191992
Manufacturer:	GUNZE LIMITED

6. Indications for Use

PELNAC® 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, partial thickness burns, and skin tears), and
- draining wounds.

PELNAC® Meshed Bilayer Wound Matrix may be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.

7. Device Description

PELNAC® Meshed Bilayer Wound Matrix is a collagen-based wound matrix that consists of two layers: a porcine derived sponge layer and a silicone film layer. Slits are added to the silicone and collagen layers to aid in the drainage of exudate. When applied to full-thickness skin defects, PELNAC® provides a scaffold for cellular invasion and capillary growth. The device 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® Meshed Bilayer Wound Matrix has the same intended use and indications for use as the predicate device INTEGRA™ Meshed Bilayer Wound Matrix (K081635). The subject and predicate device employ the same mode of action in that both devices contain a wound matrix of porous sponge-like material of animal derived collagen that serves as a scaffold for cellular invasion and capillary growth.

Table 5-1 compares PELNAC® Meshed Bilayer Wound Matrix to the predicate device with respect to their indications for use and technological characteristics 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 device are also included in **Table 5-1**.

Table 5-1 – Substantial Equivalence Comparison of PELNAC® Meshed Bilayer Wound Matrix to the Predicate Device

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device
Device Name	PELNAC® Meshed Bilayer Wound Matrix	INTEGRA™ Meshed Bilayer Wound Matrix	-	PELNAC™ Bilayer Wound Matrix
Manufacturer	GUNZE LIMITED	Integra Life Sciences	-	GUNZE LIMITED
510(k) #	K213498	K081635	-	K191992
Product Code	KGN	KGN	Same	KGN
Indications for Use	PELNAC® 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, partial thickness burns, and skin tears), and draining wounds. PELNAC® Meshed Bilayer Wound Matrix may be used in conjunction with negative pressure wound therapy. 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 bums, and skin tears) and draining wounds. The device may be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.	Same	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.

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device
Construction	Bilayer	Bilayer	Same	Bilayer
Form	Sheet	Sheet	Same	Sheet
Materials	Top layer: silicone film. Bottom layer: porcine derived collagen sponge.	Top layer: polysiloxane (silicone). Bottom layer: porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan.	Different. Therefore, the reference device was added.	Top layer: silicone film. Bottom layer: porcine derived collagen sponge.
Meshed (fenestrated) Structure	Yes	Yes	Same	Available with or without.
Mode of Action	Collagen sponge is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur. The scaffold is eventually remodeled as the patient's cells rebuild the damaged site.	Collagen sponge is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur. The scaffold is eventually remodeled as the patient's cells rebuild the damaged site.	Same	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur. The scaffold is eventually remodeled as the patient's cells rebuild the damaged site.
Single Use	Yes	Yes	Same	Yes
Supplied Sterile	Yes (EO) SAL 10^{-6}	Yes (radiation) SAL 10^{-6}	Similar	Yes (EO) SAL 10-6
Shelf Life	36 months	24 months	Similar	36 months

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device
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	50 x 50 mm 100 × 125 mm 100 × 250 mm 200 × 250 mm	Similar. The sizes of the subject device fall within the size range of the predicate device and are the same as the reference device.	20 × 30 mm 40 × 30 mm 40 × 60 mm 82 × 60 mm 82 × 90 mm 82 × 120 mm 120 × 240 mm 200 × 240 mm
Biological Evaluation	Conforms with ISO 10993-1 and FDA guidance.	Performed	Similar	Performed. Conforms with ISO 10993-1 and FDA guidance.
Collagen Viral Inactivation	Conforms with FDA guidance.	Performed	Similar	Performed. Conforms with FDA guidance.
Physical and Chemical Properties Testing	Conforms with product specification.	Performed	Similar	Performed. Conforms with product specification.
Non-Clinical Performance Testing	Conforms with product performance requirements including for new use in conjunction with negative pressure wound therapy.	Performed	Similar	Performed. Conforms with product performance requirements.

9. Non-Clinical Performance Data

The following non-clinical performance testing was conducted on PELNAC® Meshed Bilayer Wound Matrix. Results confirm that the product 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

      (The animal tissue sourcing of the subject device was evaluated following the recommendations of the above referenced FDA guidance document.)
    - FDA Guidance Document – *Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin* – 1998

      (The viral safety evaluation of the subject device was evaluated following the recommendations of the above referenced FDA guidance document.)

      Except for new viral inactivation studies performed on the subject device, all other animal tissue testing was leveraged from the reference device (K191992).
- 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, *Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing Within a Risk Management Process*

      (The biocompatibility of the subject device was evaluated following the recommendations of the above referenced FDA guidance document.)

        - Implantation
        - Cytotoxicity
        - Skin Sensitization
        - Intracutaneous Reactivity
        - Material Mediated Pyrogenicity
        - Chemical Characterization
        - Toxicological Risk Assessment

      All biocompatibility testing of the subject device was leveraged from the reference device (K191992).
- Sterilization, Packaging and Shelf Life:
    - ISO 11135, *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*
    - ISO 11607-1, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
    - ASTM F1886, *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*
    - USP <85> Bacterial Endotoxin Test

All sterilization, packaging and shelf life testing of the subject device was leveraged from the reference device (K191992).

- Performance Testing:
    - Pore Size
    - Degree of Cross-Linking
    - Water Vapor Transmission
    - Drapeability
    - Heavy Metal Content
    - Suture Retention
    - Tensile Strength

PELNAC® Meshed Bilayer Wound Matrix has only been demonstrated for use in conjunction with the InfoV.A.C. NPWT Therapy System in continuous and intermittent mode. Side-by-side testing was conducted between the subject device in conjunction with NPWT, the predicate device in conjunction with NPWT, and NPWT without a wound matrix group. This testing used a simulated wound model in conjunction with a simulated wound fluid. The tests consisted of Pressure Stability, Fluid Removal, Long-Term performance and Alarm Function (on the InfoV.A.C. NPWT Therapy System in continuous and intermittent mode).

- Risk Analysis:
    - ISO 14971, *Medical devices - Application of risk management to medical devices*

10. Clinical Performance Data

Not applicable to this submission.

11. Substantial Equivalence Conclusion

PELNAC® Meshed Bilayer Wound Matrix has the same intended use and indications for use as INTEGRA™ Meshed Bilayer Wound Matrix. Any minor differences in the technological features of the subject device when compared to the predicate device have been evaluated through non-clinical performance testing and other verification and validation activities. PELNAC® Meshed Bilayer Wound Matrix is substantially equivalent to the predicate device.