February 9, 2022

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

Re: K213573
Trade/Device Name: PELNAC Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 26, 2021
Received: November 10, 2021

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,

For Julie Morabito
Acting 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)*
K213573

Device Name
PELNAC® Wound Matrix

Indications for Use *(Describe)*
PELNAC® Wound Matrix 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, partial thickness 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® Wound Matrix

1. Submission Sponsor

GUNZE LIMITED
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Contact: Mr. Hidenori Nishioka
Title: Regulatory Affairs

2. Submission Correspondent

Emergo Global Consulting, LLC
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Austin, TX 78746
Contact: Mr. Stuart R. Goldman
Title: Sr. Consultant RA/QA

3. Date Prepared

February 7, 2022

4. Device Identification

Type of 510(k):	Traditional 510(k)
Trade Name:	PELNAC® 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:	AVAGEN Wound Dressing

510(k) No.: K022127
Manufacturer: Integra Life Sciences

The following reference devices have also been included in this submission.

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

Trade Name: Integra® Wound Matrix (Thin)
510(k) No.: K113104
Manufacturer: Integra Life Sciences

6. Indications for Use

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

The device is intended for one-time use.

7. Device Description

PELNAC® Wound Matrix is a single layer wound matrix of 100% atelocollagen sponge derived from porcine Achilles tendon that is applied directly to the wound surface. When applied to full-thickness skin defects, PELNAC® Wound Matrix provides a scaffold for cellular invasion and capillary growth. The device is offered in sheet form of various sizes and in two levels of thickness and is provided terminally sterilized by ethylene oxide. PELNAC® Wound Matrix 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® Wound Matrix has the same indications for use as the predicate device AVAGEN Wound Dressing (K022127). The subject and predicate device employ the same mode of action in that both devices contain a single layer 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® 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 devices are also included in **Table 5-1**.

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

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device #1	Reference Device #2
Device Name	PELNAC® Wound Matrix	AVAGEN Wound Dressing	-	PELNAC™ Bilayer Wound Matrix	Integra® Wound Matrix (Thin)
Manufacturer	GUNZE LIMITED	Integra Life Sciences	-	GUNZE LIMITED	Integra Life Sciences
510(k) #	K213573	K022127	-	K191992	K113104
Product Code	KGN	KGN	Same	KGN	KGN
Indications for Use	PELNAC® Wound Matrix 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, partial thickness 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 bums, and skin tears) and draining wounds. 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.	Integra® Wound Matrix (Thin) 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 bums, and skin tears) and draining wounds. The device is intended for one-time use.

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device #1	Reference Device #2
Construction	Single layer	Single layer	Same	Bilayer	Single layer
Form	Sheet	Sheet	Same	Sheet	Sheet
Materials	Collagen sponge porous matrix of porcine (Achilles) tendon.	Collagen sponge porous matrix of bovine tendon + glycosaminoglycn.	Different. Therefore, Reference Device #1 was added to the substantial equivalence discussion for the different source of animal tissue used.	Silicone film, synthetic gauze, and collagen sponge porous matrix of porcine (Achilles) tendon.	Collagen sponge porous matrix of bovine tendon + glycosaminoglyca.
Meshed (fenestrated) Structure	No	No	Same	Available with or without.	No
Mode of Action	Collagen sponge is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur.	Collagen sponge is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur.	Same	Collagen sponge layer is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur.	Collagen sponge is applied to the wound surface and acts as a scaffold for cellular invasion and capillary growth to occur.
Single Use	Yes	Yes	Same	Yes	Yes

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device #1	Reference Device #2
Supplied Sterile	Yes (EO)	Yes (radiation)	Similar	Yes (EO)	Yes (radiation)
Shelf Life	36 months	24 months	Similar	36 months	24 months
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 50 100 × 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	50 x 50 mm 100 × 125 mm 100 × 250 mm 200 × 250 mm
Thickness	3 mm and 1.5 mm (thin)	0.8 mm	Different. Therefore, Reference Device #2 was added to the substantial equivalence discussion to add a thin version of the device. The drapability of the subject device has been demonstrated through performance testing.	3 mm	0.4 mm
Biological Evaluation	Conforms with ISO 10993-1 and FDA guidance.	Performed	Similar	Performed. Conforms with ISO 10993-1 and FDA guidance.	Performed

Attributes	Subject Device	Predicate Device	Similarities / Differences	Reference Device #1	Reference Device #2
Collagen Viral Inactivation	Conforms with FDA guidance.	Unknown	Similar	Performed. Conforms with FDA guidance.	Unknown
Physical and Chemical Properties Testing	Conforms with product specification.	Unknown	Similar	Performed. Conforms with product specification.	Unknown
Non-Clinical Performance Testing	Conforms with product performance requirements. New drapeability testing was also performed for the subject device and compared to Reference Device #2. Suture retention testing is not required for the subject device as it is not to be sutured to the wound bed, and instead is held in place by way of appropriate secondary dressings as described in its instructions for use.	Unknown	Similar	Performed. Conforms with product performance requirements.	Performed

9. Non-Clinical Performance Data

The following non-clinical performance testing conducted on PELNAC™ Bilayer Wound Matrix (K191992) is being leveraged for PELNAC® 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
  - 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, *Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing Within a Risk Management Process*
    - Implantation
    - Cytotoxicity
    - Skin Sensitization
    - Intracutaneous Reactivity
    - Material Mediated Pyrogenicity
    - Chemical Characterization
    - Toxicological Risk Assessment
- Sterilization, Packaging and Shelf Life:
  - ISO 11135
  - ISO 11607-1
  - ASTM F1886
  - USP <85> Bacterial Endotoxin Test
- Performance Testing:
  - Pore Size
  - Degree of Cross-Linking
  - Drapeability
  - Heavy Metal Content
- Risk Analysis:
  - ISO 14971

10. Clinical Performance Data

Not applicable to this submission.

11. Substantial Equivalence Conclusion

PELNAC® 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 non-clinical performance testing and other verification and validation activities. PELNAC® Wound Matrix as designed and manufactured by GUNZE LIMITED is substantially equivalent to the predicate device, AVAGEN Wound Dressing.