September 1, 2021

Omeza, LLC
% Randy Prebula
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, District of Columbia 20004

Re: K211972
Trade/Device Name: Omeza Collagen Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 24, 2021
Received: June 24, 2021

Dear Randy Prebula:

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,

Lixin Liu, PhD
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. 0910-0120Expiration Date: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*

K211972

Device Name

Omeza® Collagen Matrix

Indications for Use *(Describe)*

Omeza® Collagen 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, superficial partial thickness burns, skin tears)
- 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

Omeza® Collagen Matrix

K211972

Submitter's name and address:

Omeza, LLC
25 South Osprey Avenue
Sarasota, Florida 34231

Contact person and telephone number:

Thomas Gardner Chief
Executive Officer
Telephone: 941-780-5274 Email:
tgardner@omeza.com

Date Summary was prepared:

August 23, 2021

Product Name:

Proprietary Name:	Omeza® Collagen Matrix
Common Name:	Wound Dressing
Device Classification Name:	Dressing, Wound, Drug
Regulatory Classification:	Unclassified
Product Code:	FRO

Predicate Device: SweetBio Apis (K182725)
Reference Devices: INTEGRA™ Flowable Wound Matrix (K072113)
Kerecis MariGen Wound Dressing (K132343)
Southwest Technologies Stimulen Collagen (K030774)

Product Description:

Omeza® Collagen Matrix (OCM) is a wound care matrix comprised of hydrolyzed fish collagen infused with cod liver oil, which acts as an anhydrous skin protectant, and other plant-derived oils and waxes. When applied to a wound surface, the matrix is naturally incorporated into the wound over time. Omeza® Collagen Matrix is designed for intimate contact with both regular and irregular wound beds to providea conducive environment for the patient's natural wound healing process.

Intended Use/Indications for Use:

Omeza® Collagen 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, superficial partial thickness burns, skin tears)
- Draining wounds

The device is intended for one-time use.

Comparison with the Predicate Device:

Omeza® Collagen Matrix and the predicate device SweetBio Apis (K182725) have the same intended use, namely to manage wounds by providing an animal-derived collagen product that is biodegradable and incorporates into the surrounding tissue during the body's natural wound healing processes. Both supplement the collagen constituent with additional biocompatible materials to achieve a final product that covers and protects the wound, assists in managing wound exudate, and maintains a moist wound environment. Both products are supplied sterile and for single use, and have very similar specific indications for use.

As can be seen from the substantial equivalence table below, the comparison to the predicate device shows no new questions of safety or effectiveness. Both products rely primarily on collagen to achieve the intended use, and based on the function of the additional materials in each product, the intended use of the Omeza Collagen Matrix is the same compared to that of the predicate. Additionally, performance testing data shows that there are no different questions of safety or effectiveness.

	Omeza® Collagen Matrix (Subject product)	**SweetBio Apis (predicate) (K182725)**
Indications for Use		
Product Code	FRO	FRO
Indications for Use	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, superficial partial thickness burns, and skin tears), draining wounds. The device is intended for one-time use.	Indicated for use in management of wounds including: full and partial thickness wounds, pressure ulcers (stages I-IV), venous stasis ulcers, diabetic ulcers, abrasions, surface wounds, traumatic wounds (healing by secondary intention), donor site wounds, surgical wounds
Rx	Yes	Yes
Single use	Yes	Yes
Technological Characteristics		
Sizes	Single-use vial of 1.6g (2mL); volume covers 3cm x 6cm area (18 cm^2)	Sheet form, available in sizes 16 x16mm, 25x 25mm, 50 x 50mm
Intimate contact with wound bed	Yes	Yes
Technological Features	Collagen and other components manufactured to gel-like consistency, soft at ambient temperature, and applied topically	Collagen derivative and other components manufactured to sheet, softened with saline, and applied topically

Collagen Source	Whitefish skin collagen Types I, II, III, IV	Porcine skin collagen derivative(gelatin)
Collagen product particle size	Collagen particles of ≤1000µm in diameter	Collagen particle derivative (gelatin)
Applied hydrated or flowable	Yes	Yes
Contains salt when applied	Yes (Sea salt)	Yes (Final product softened with saline before topical application)
Additional materials of composition	Cod liver oil, plant-derived oils and waxes, and process aids	Manuka honey and hydroxyapatite
Absorbable	Fully absorbable	Fully absorbable
Moist environment	Maintains moist wound environment	Maintains moist wound environment
Wound protection	Protects the wound tissue	Protects the wound tissue
Supplied sterile?	Yes (E-beam)	Yes (Gamma)
Shelf life	Shelf stable at room temperature	Shelf stable at room temperature
Additional performance testing	Porosity, mechanical, endotoxin, chemical composition, and distribution testing; sterilization validation	Porosity, mechanical, endotoxin, chemical composition, and distribution testing; sterilization validation

The main differences between the Omeza Collagen Matrix and the predicate are the specific collagen source – Omeza uses whitefish skin-derived collagen and SweetBio Apis uses porcine skin-derived collagen – and the specific identity of the supplemental components, which serve the same fundamental purpose in enabling each wound dressing to achieve the shared intended use. The key questions of safety of the animal-derived material and effectiveness of achieving the intended use remain the same for both products, and are fully addressed for the Omeza Collagen Matrix through submitted performance testing. They are additionally supported by clearance of the reference devices with the same intended use and similar indications:

- MariGen Wound Dressing (K132343), which is also derived from fish collagen;
- Stimulen® Collagen Gel (K030774) which also contains collagen delivered in a gel-like consistency; and
- INTEGRA Flowable Wound Matrix (K072113), which is also gel-like. In particular, Omeza® Collagen Matrix and the INTEGRA Flowable Wound Matrix (K072113) manage wounds by providing collagen particles of similar diameter in a gel-like consistency applied topically in a sterile, single-use application. Both products are designed to conform to the wound bed, achieving intimate contact with the surface, and are ultimately incorporated into the wound during the natural healing process.

Performance Data:

The following testing was performed to demonstrate substantial equivalence:

Biocompatibility Testing

All biocompatibility endpoints required according to ISO 10993-1 and FDA's corresponding 2016guidance were evaluated with favorable results. Testing was performed in the following categories:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Genotoxicity

- Material-mediated pyrogenicity

Clinical Studies

A Skin Prick Study was performed in the US in accordance with Good Clinical Practice Standards. The single-center, monadic, one-day study enrolled 25 subjects. The study evaluated Collagen Matrix for the potential of an immediate allergic reaction following a one-day Skin Prick Method Study. The test article, a positive control (1.0 mg/mL histamine base), and a negative control (aqueous negative control) were tested on subjects using the "Allergy Diagnostic Testing: An Updated Practice Parameter" skin prick test method. During this study, no immediate allergic reaction to the test product was observed for any subjects. Therefore, no potential allergenicity of the test product was observedunder the conditions of this study.

A Human Repeat Insult Patch Test was performed in the US to Good Clinical Practice Standards. The study design was based on a modified Human Repeat Insult Patch Test. The study was single site, evaluator-blinded using a within-subject randomization design. The study had (58) subjects enrolled. Omeza® Collagen Matrix was evaluated for the potential to cause irritation and sensitization compared to that of a negative control (0.9% aqueous sodium chloride) based on a modified human repeat insult patch test. Under the conditions of this study, the test product showed to be safe for use with no side effects.

Animal Studies

Two wound healing studies were conducted to assess the implantation and the wound healing endpoints of Omeza® Collagen Matrix on porcine wounds. The first swine study compared the subject product to saline. The two products were applied to 10 full-thickness circular wound sites (approximately 3.0 cm in diameter) on four animals, with 14 and 25 day evaluations followed by pathology and independent expert review. The second swine study compared an exaggerated dose of Omeza Collagen Matrix to Hollister Endoform Dermal Template (K092096), with the products applied to 10 full-thickness circular wound sites (approximately 2.0 cm in diameter) on two animals. The final wound evaluation occurred at 24 days, followed by pathology and independent expert review. Both studies showed no evidence of impairment of wound healing with the use of Omeza® Collagen Matrix, and demonstrated that the subject product was safe and did not trigger adverse biological reactions inthe animals.

Additional Testing (Bench)

- Extrusion: Omeza performed testing on representative lots to quantify the amount of producta typical user can extrude from a vial.
- Final Product Coverage: The time required for the product to cover 18 sq. cm – target coveragefor one vial – was calculated in a simulated model.
- Product Characterization under Environmental Conditions: Surface morphology of Omeza Collagen Matrix was imaged at varying magnifications using Scanning Electron Microscopy (SEM), to observe andconfirm microscopic and macroscopic stability of the OCM structure.
- Interaction with Wound Exudate: SEM was employed to compare the surface structure/morphology of sterile, dry OCM to OCM immersed in solutions of varying salinity concentrations, simulating moist wound exudate conditions.
- Sterilization/endotoxins: OCM vials are sterilized using a process validated per ANSI/AAMI/ISO 11137-2. Biologic testing for sterilization validation was also

performed. Endotoxin testing confirmed an acceptable level of endotoxins in the final product.

- Viral Inactivation: Three viral inactivation studies were performed on the OCM utilizing a panel of model viruses per ISO 22442 Part 3 (Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents).
- Shelf Life: OCM meets requirements for a 9-month shelf life, based on product tested at theend of this period passing all finished product specifications.
- Collagen Characterization: Standard ELISA techniques were used to determine the types ofcollagen in OCM.
- Lot-to-Lot Consistency: Testing of samples from representative lots demonstrated lot-to-lot consistency of all OCM raw materials.
- Cod Liver Oil Identification and Quantification: Fatty Acid Methyl Ester analysis following AOAC 996.06 was conducted on representative lots to quantify the Cod Liver Oil (CLO) in thefinal product.
- Elastic Modulus: The product's rheological properties were evaluated by analyzing elastic modulus, with results showing that this feature of the final product is consistent across lots.
- Extractables and Leachables: Extractables testing was completed on the OCM primary and secondary packaging system, following ISO 10993 and USP 1663. No extractable compounds were detected in the product primary packaging above the analytical evaluationthreshold.
- Final Product Specifications: Representative samples of final, sterilized OCM were analyzed for conformance to pre-defined specifications for quantity (%w/w) of collagen, pH, specific gravity, heavy metals, product structure, and bioburden.

Conclusion:

Omeza® Collagen Matrix functions as intended, and is as safe and effective as SweetBio Apis (K182725). As explained above, OCM has the same intended use and similar indications for use, and similar key technological and design characteristics and mechanism of action. The minor differences between the subject and predicate products do not raise different questions of safety or effectiveness, as supported by performance data on the subject product and prior clearance of the reference devices. Thus, Omeza® Collagen Matrix is substantially equivalent with the predicate device.