DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2016

Collagen Matrix, Inc.
Ms. Gloria Zuclich
Senior Manager of Regulatory Affairs
15 Thornton Road
Oakland, New Jersey 07436

Re: K152600
Trade/Device Name: Collagen Dental Wound Dressings
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 24, 2016
Received: May 26, 2016

Dear Ms. Zuclich:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
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for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K152600

Device Name: Collagen Dental Wound Dressings

Indications for Use:

Collagen Dental Wound Dressings are indicated for the management of oral wounds and sores, including:

- Denture sores
- Oral ulcers (non-infected or viral)
- Periodontal surgical wounds
- Suture sites
- Burns
- Extraction sites
- Surgical wounds
- Traumatic wounds

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

1. Applicant Information

Applicant Name:	Collagen Matrix, Inc.
Address:	15 Thornton Road Oakland, New Jersey 07436 USA
Telephone:	(201) 405-1477 Ext. 317
Fax:	(201) 405-1355
Contact Person:	Gloria Zuclich Director of Regulatory Affairs
Date Prepared:	June 2, 2016

2. Name of the Device

Device Trade Name:	Collagen Dental Wound Dressings
Device Common Name:	Dental Wound Dressings
Device Classification Name:	Dressing, Wound, Collagen Product Code KGN Unclassified

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Primary Predicate:	K122115	Collagen Dental Wound Dressing Collagen Matrix, Inc.
Reference Predicate:	K142712	Dental Collagen Wound Dressing (NovaTape and NovaPlug) NovaBone Products, LLC

4. Description of the Device

Collagen Dental Wound Dressings are absorbent, porous, collagen matrices engineered from purified collagen derived from bovine dermis tissue. The Collagen Dental Wound Dressings are applied directly to the wound and protect the wound and delicate new tissue. Collagen Dental Wound Dressings can be removed, replaced or left in situ. If left in situ the dressings will be essentially resorbed in 30 days. Collagen Dental Wound Dressings are available in tape, sponge and plug form, and are supplied sterile, non-pyrogenic and for single use only.

5. Intended Use

Collagen Dental Wound Dressings are indicated for the management of oral wounds and sores, including:

- Denture sores
- Oral ulcers (non-infected or viral)
- Periodontal surgical wounds
- Suture sites

- Burns
- Extraction sites
- Surgical wounds
- Traumatic wounds

6. Summary/Comparison of Technical Characteristics

Collagen Dental Wound Dressings have been determined to be substantially equivalent to the predicate devices having similar technological characteristics as follows:

Parameter	Collagen Dental Wound Dressings (This submission)	Collagen Dental Wound Dressing (Predicate, K122115)	Dental Collagen Wound Dressings (Predicate, K142712)
510(k)	Not assigned	K122115	K142712
Indications for Use	Intended for use in the management of oral wounds and sores, including: • Denture Sores • Oral Ulcers (non-infected or viral) • Periodontal surgical wounds • Suture sites • Burns • Extraction sites • Surgical Wounds • Traumatic Wounds	Intended for use in the management of oral wounds and sores, including: • Denture Sores • Oral Ulcers (non-infected or viral) • Periodontal surgical wounds • Suture sites • Burns • Extraction sites • Surgical Wounds • Traumatic Wounds	Intended for use in the management of oral wounds and sores, including: • Denture Sores • Oral Ulcers (non-infected or viral) • Periodontal surgical wounds • Suture sites • Burns • Extraction sites • Surgical Wounds • Traumatic Wounds
Material	Purified Collagen	Purified Collagen	Purified Collagen
Collagen Source	Bovine Dermis	Porcine Tendon	Bovine Dermis
Form	Porous Collagen Matrix	Porous Collagen Matrix	Porous Collagen Matrix
Color	White to off-white	White to off-white	White to off-white
Shapes	Rectangular and Cylindrical	Rectangular and Cylindrical	Rectangular and Cylindrical
Sizes	25mm x 75mm x 1mm 20mm x 40mm x 3mm 10mm (ID) x 20mm (L)	25mm x 75mm x 1mm 20mm x 40mm x 3mm 10mm (ID) x 20mm (L)	25mm x 75mm x 1mm 20mm x 40mm x 3mm 10mm (ID) x 20mm (L)
Absorbency	Absorbs local wound fluids upon application	Absorbs local wound fluids upon application	Absorbs local wound fluids upon application
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Not Known
Sterilization	Gamma Irradiation, SAL 10^{-6}	Gamma Irradiation, SAL 10^{-6}	E-beam irradiation, SAL 10^{-6}
Single Use/ Reuse	Single use only	Single use only	Single use only
Packaging	Single barrier (blister tray or Tyvek pouch)	Single barrier (blister tray)	Single barrier (blister tray or Tyvek pouch)

7. Discussion of Non-clinical Testing

The substantial equivalence of Collagen Dental Wound Dressings and its predicates was demonstrated based on *in vitro* characterization studies, biocompatibility studies and an animal resorption study.

Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidelines as follows:

ISO 22442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management

ISO 22442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling

ISO 22442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents

ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2009 Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization

Non-clinical Testing Conducted

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate devices. A series of bench tests were conducted which included an evaluation of physical, chemical, and biological properties as indicated.

Test	**Results**
Composition	Purified Collagen
Dimensions	Dimensions similar to predicate device
Thickness	Thickness similar to predicate device
Density	Density similar to predicate device
Weight	Weight similar to predicate device
Absorbency	Absorbency similar to predicate device
Pyrogenicity	Non-Pyrogenic
Residues	Within acceptable limits
pH	pH similar to predicate device
Absorbency	Absorbency similar to predicate device
Hydrothermal transition temperature	Hydrothermal transition temperature similar to predicate device.

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess safety of the Collagen Dental Wound Dressings as a topical material. The biocompatibility testing performed is summarized in the table below.

Test	Test Method / Model	Results
Cytotoxicity	Agarose Overlay, ISO 10993-5 ISO Elution Method, ISO 10993-5	Non-cytotoxic
Sensitization	Guinea Pig Maximization, ISO 10993-10	No evidence of causing delayed dermal contact sensitization in the guinea pig.
Intracutaneous Reactivity	Intracutaneous Study in Rabbits, ISO 10993-10	Under the conditions of the study, there was no erythema or edema from the extract injected intracutaneously into rabbits.
Pyrogenicity	USP (151) Rabbit Pyrogen Study	The test article was judged as non-pyrogenic.

An *in vivo* resorption study utilizing a rat subcutaneous model was conducted to evaluate the device as compared to its predicate device with regards to device resorption.

A viral inactivation study was performed to ensure the viral safety of the product.

8. Conclusion of Non-clinical Studies

The predicate devices were cleared based on the results of non-clinical data. The results of the non-clinical tests conducted demonstrate that the device is substantially equivalent to the legally marketed predicate device.