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

July 25, 2017

Strukmyer Medical
Pamela Liberto
Director of QA
1801 Big Town Blvd Suite #100
Mesquite, Texas 75149

Re: K171645
Trade/Device Name: CoMatryx Collagen Wound Dressing 1 gram pouch, CoMatryx Collagen Wound Dressing 1 gram vial, CoMatryx Collagen Wound Dressing 10 gram bottle
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 2, 2017
Received: June 5, 2017

Dear Pamela Liberto:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171645

Device Name

CoMatryx Collagen Wound Dressing

Indications for Use *(Describe)*

CoMatryx Collagen Wound Dressing may be used in the management of partial and full thickness wounds, pressure (stage I-IV) and venous ulcers, ulcers caused by mixed vascular etiologies, venous stasis and diabetic ulcers, 1st and 2nd degree burns, cuts, abrasions, and surgical wounds.

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

I. ADMINISTRATIVE

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Strukmyer Medical
1801 Big Town Blvd, Suite 100
Mesquite, Texas 75149

Telephone No.: 214-275-9595
Facsimile No.: 214-275-6748

Contact Person: Pamela Liberto
E-Mail: pliberto@strukmyer.com

Date Prepared: July 20, 2017

II. DEVICE NAME

Proprietary Name: CoMatryx Collagen Wound Dressing

Common or Usual Name: Collagen Wound Dressing

Classification: Dressing, Wound, Collagen

Regulatory Class: Unclassified

Product Code: KGN

III. PREDICATE DEVICE:

CollaTek Powder K012990, Biocore Medical Technologies, Inc. (Now sold under the name Medifil II Particles by Human BioSciences, Inc., Gaithersburg, MD 20878).

IV. DEVICE DESCRIPTION:

Collagen Wound Dressing, a native bovine Type I Collagen which, when applied to a wound surface, absorbs wound fluid and maintains a moist wound

environment in the management of wound healing. The CoMatryx Collagen Wound Dressing is provided sterile in the following patient ready configurations:

- 10 gram Bottle
- 1 gram Vial
- 1 gram pouch

V. INTENDED USE

CoMatryx Collagen Wound Dressing may be used in the management of partial and full thickness wounds, pressure (stage I-IV) and venous ulcers, ulcers caused by mixed vascular etiologies, venous stasis and diabetic ulcers, 1st and 2nd degree burns, cuts, abrasions, and surgical wounds.

VI. COMPARISON TO PREDICATE DEVICE

CoMatryx Collagen Wound Dressing is Type 1 bovine collagen which absorbs wound fluid, maintains a moist wound environment and is equivalent to predicate products currently in commercial distribution.

Both Predicate and Strukmyer CoMatryx Collagen Wound dressings are derived from Type 1 bovine collagen. Infrared Spectroscopy (IR) Scan provided as attachment of predicate and Strukmyer Collagen Wound dressings match identically proving that material composition of both products are same.

Both predicate and Strukmyer collagen dressings are ground to powder.

This formulation does not affect the intended use or alter the fundamental scientific technology of the device.

By comparing product characteristics such as physical shape, IR Spectrum, pH, color, absorbency and moisture content of both predicate and Strukmyer Collagen Wound dressings, it can be concluded that Strukmyer Collagen Wound dressings is substantially equivalent to the predicate device.

The CoMatryx Collagen Wound Dressing is as safe and effective as the predicate devices referenced herein. CoMatryx Collagen Wound Dressing has similar intended uses, technological characteristics, and basic principles of operation as the aforementioned predicate device and raises no new issues of safety or effectiveness. CoMatryx Collagen Wound Dressing is substantially equivalent to the predicate device. See below for a comparison table.

Parameters	**CoMatryx Collagen Wound Dressing**	**CollaTek* Powder (aka Medifil II Particles) BioCore K012990**	**Test Methods (standards)**
Indications for use	May be used in the management of: • Partial and full thickness wounds • Pressure (stage I-IV) and venous ulcers • Ulcers caused by mixed vascular etiologies • Venous stasis and diabetic ulcers • 1st and 2nd degree burns • Cuts, abrasions, and surgical wounds	May be used in the management of: • Partial and full thickness wounds • Pressure (stage I-IV) and venous ulcers • Ulcers caused by mixed vascular etiologies • Venous stasis and diabetic ulcers • 1st and 2nd degree burns • Cuts, abrasions, and surgical wounds	510k Comparison
Product Code	KGN	KGN	510K
Rx	Yes	Yes	510K
Physical Shape	Powder	Powder	510K
Color	White to off-white	White to off-white	Visual
Single Use	Single use only	Single use only	510K
Package Sizes	1 gram in vial 1 gram in pouch 10 grams in bottles	1 gram in vial 1 gram in pouch 10 grams in bottles	510K
Water Absorption Capacity	NLT 20 times its weight in USP *Purified Water*	NLT 20 times its weight in USP *Purified Water*	Strukmyer Procedure #HOMA-AFTP5R
Particle Size	Powder	Powder	Strukmyer Procedure #HOMA-AFTPRK
Product Type	Collagen	Collagen	510K
Product Description	Type I Bovine Collagen	Type I Bovine Collagen	510K
Animal Tissue	Dermis	Dermis	510K
Sterile	Yes	Yes	510K
Sterilization Method	E-Beam	E-Beam	510K
Product Classification	unclassified	unclassified	FDA
Moisture content	≤ 17%	≤ 17%	Strukmyer Procedure #HOMA-9YQRG8
pH	≥ 2.5	≥ 2.5	Strukmyer Procedure # HOMA-9Z9HUM
InfraRed Spectroscopy Scan	Characteristic of Material, comparable	Characteristic of Material, comparable	Strukmyer Procedure # HOMA-A2CJEJ
SDS-PAGE Analysis	Characteristic of Material, comparable	Characteristic of Material, comparable	Alamo Labs, Inc. Report#3480-01

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

Biocompatibility testing of CoMatryx Collagen Wound Dressing has been conducted in accordance with the testing standards of ISO 10993: "Biological Evaluation of Medical Devices." Biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization – Guinea Pig
- Intracutaneous Irritation Test
- Acute Systemic Toxicity

Animal Study

Since the MEM Endpoint Dilution Test (in-vitro) indicated cytotoxic effect for CoMatryx Collagen Wound Dressing, a Wound Healing Study as requested by FDA was conducted to analyze the effect of CoMatryx Collagen on porcine wounds. The Wound Healing study shows no evidence of impairment of wound healing with the use of CoMatryx Collagen wound dressing.

VIII. CONCLUSION

Based on a comparison of composition, technological characteristics, intended use and biocompatibility test results, we conclude that the CoMatryx Collagen Wound Dressing performs at least as well as the predicate device. The CoMatryx Collagen Wound Dressing is therefore considered to be substantially equivalent to the above-mentioned predicate device.

End of Summary