December 1, 2023

Strukmyer Medical, LLC.
% Richard Hamer
Consultant
Richard Hamer Associates LLC
705 Spring Lakes Blvd
Bradenton, Florida 34210

Re: K232758
Trade/Device Name: Comatryx OTC Collagen Wound Dressing
Regulatory Class: Unclassifed
Product Code: KGN
Dated: October 2, 2023
Received: October 3, 2023

Dear Richard Hamer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K232758

Device Name

CoMatryx OTC Collagen Wound Dressings

Indications for Use *(Describe)*

The device is intended for the management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns

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.

K232758

510(k) SUMMARY

I. ADMINISTRATIVE

Submitter:

Strukmyer Medical LLC
1801 Big Town Blvd, Suite 100
Mesquite, Texas 75149
Telephone: 214-275-9595

Contact Person: Christian Quinto
E-Mail: cquinto@strukmyer.com

Date Prepared: December 1, 2023

II. DEVICE NAME

Proprietary Name: CoMatryx OTC Collagen Wound Dressing

Common or Usual Name: Collagen Wound Dressing

Regulatory Class: Unclassified

Product Code: KGN

III. PREDICATE DEVICES

Cellusheet Dressing and Cellufil Particles, K213092, Human Biosciences, Inc.
Comatryx Collagen Wound Dressing, K171645, Strukmyer Medical, LLC (reference device)

IV. DEVICE DESCRIPTION

CoMatryx OTC Collagen Wound Dressing is a native bovine Type I Collagen which, when applied to a wound surface in powder or pad form, absorbs wound fluid and maintains a moist wound environment. The CoMatryx OTC powder and pads are provided sterile in the following configurations:

- 1 gram powder in 1 pouch
- 2”x2,” 3”x4,” and 8”x12” pad in pouch

V. INDICATIONS FOR USE

CoMatryx OTC Collagen Wound Dressings are indicated for the management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor bums.

VI. COMPARISON TO PREDICATE DEVICE

CoMatryx OTC Collagen Wound Dressings are composed of Type 1 bovine collagen which absorbs wound fluid, maintains a moist wound environment and are equivalent to predicate products currently in commercial distribution.

Both the predicate device and CoMatryx OTC Collagen Wound Dressings are derived from Type 1 bovine collagen dressings and supplied in powder form or as pads of various sizes.

The CoMatryx OTC Collagen Wound Dressings have the same intended uses, technological characteristics, and basic principles of operation as the predicate device and raise no new issues of safety or effectiveness. See below for a comparison table:

Parameters	Subject Device CoMatryx OTC Collagen Wound Dressings	Predicate Device Cellufil and Cellusheet Wound Dressings K213092
Manufacturer	Strukmyer Medical LLC	Human Biosciences Inc.
Intended Use	Management of wounds	Management of wounds
Indications for Use	Management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns	Management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns.
Product Code	KGN	KGN
Device Class	Unclassified	Unclassified
Rx or OTC	OTC	OTC
Physical Shape	Powder and Pads	Powder and Pads
Usage	Single patient use only	Single patient use only
Package Sizes	1 gram in 1 pouch 2"x2", 3"x4", 8"x12" pads	1 gram in 1 pouch 2"x2", 3"x4", 8"x12" pads
Product Description	Type I Bovine Collagen	Type I Bovine Collagen
Animal Tissue	Dermis	Dermis
Sterilization Method	E-Beam. Product supplied sterile.	E-Beam. Product supplied sterile.
Storage Condition	Store in a cool and dry space	Store in a cool and dry space
Shelf Life	Powder - 36 months Pads - 48 months	60 months

VII. PERFORMANCE DATA

Comatryx OTC Collagen Wound Dressings are identical to the predicate device except for the indications for use; therefore, testing from K171645 applies to this device.

VIII. CONCLUSION

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