January 17, 2019

Cell Constructs I, LLC
% Elizabeth O'Keefe
Regulatory Affairs Director
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K182010
Trade/Device Name: ProgenaMatrix™
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 18, 2018
Received: December 18, 2018

Dear Elizabeth O'Keefe:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anjana Jain -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: 06/30/2020

See *PRA Statement on last page.*

510(k) Number *(if known)*

K182010

Device Name

ProgenaMatrix™

Indications for Use *(Describe)*

ProgenaMatrix™ is indicated for dry and exuding partial and full thickness wounds such as: pressure (stage I-IV) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, donor sites and grafts, first and second degree burns, superficial injuries, cuts, abrasions and surgical wounds.

ProgenaMatrix™ is not intended to be used on third degree 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.

510(k) Summary of Safety and Effectiveness

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the Cell Constructs I, LLC ProgenaMatrix™ is provided below.

Date	01/16/2019
Submitted by	Cell Constructs I, LLC 2275 Northwest Pkwy SE, Suite 170 Marietta, GA 30067 Phone : 770-627-2547
510(k) Contact	Secure BioMed Evaluations Elizabeth O'Keeffe, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com
Trade Name	ProgenaMatrix™
Common Name	Dressing, Wound, Collagen
Code –Classification	KGN: Unclassified
Primary Predicate	K080949 Keratec Wound Dressings (a/k/a Keraderm, now known as Keramatrix®)
Reference Devices	K073251 Hyalomatrix®
Device Description	ProgenaMatrix™ is a clear keratin matrix derived from human hair designed to assist wound healing by facilitating a moist wound healing environment. It is packaged in a sterile, moisture-proof, peel-open pouch containing water and propylene glycol.
Intended Use	ProgenaMatrix™ is indicated for dry and exuding partial and full thickness wounds such as: pressure (stage I-IV) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, donor sites and grafts, first and second degree burns, superficial injuries, cuts, abrasions and surgical wounds. ProgenaMatrix™ is not intended to be used on third degree burns.
Technological Characteristics	The subject device has substantially equivalent technological characteristics as the predicate device and/or the reference device in terms of principles of operation, intended use, material performance, and biocompatibility.

Non-Clinical Testing	The subject device has mechanical properties substantially equivalent to the predicate device with the same intended use. The following characteristics were evaluated: • Tensile Strength • Moisture Vapor Transmission Rate • Water Transmission Rate • Degradation Potential • Manufacturing Residuals • Viral Inactivation • Protein Characterization • Removal of Contaminants

Biocompatibility Testing	• Cytotoxicity
	• Sensitization
	• Irritation
	• Acute Toxicity
	• Subacute & Subchronic Toxicity (Implantation Endpoint Assessment)
	• Endotoxin Testing
	• Pyrogenicity
	• Toxicological Risk Assessment
	  • Chronic Toxicity
	  • Genotoxicity
	  • Carcinogenicity

Clinical Testing	• Repeat Insult Patch Test • Skin Prick Test
Conclusions	ProgenaMatrix™ has the same intended use, principles of operation and substantially equivalent technological characteristics as Keratec Wound Dressing (a/k/a Keraderm, now known as Keramatrix®). While ProgenaMatrix™ differs from the predicate device in the source of keratin protein (human vs. sheep), both devices share the same mode of action in that they assist in providing a moist wound healing environment. ProgenaMatrix™ is substantially equivalent with respect to safety and effectiveness to the predicate and reference devices and does not raise different questions of safety and effectiveness.