May 11, 2020

3-D Matrix, Inc.
% Stephen Rhodes
Principal
Streamline Regulatory
3502 Dundee Driveway
Chevy Chase, Maryland 20815

Re: K193085
Trade/Device Name: PuraDERM Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 9, 2020
Received: April 9, 2020

Dear Stephen Rhodes:

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,

For Anjana Jain, Ph.D.
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. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193085

Device Name
PuraDerm Gel

Indications for Use *(Describe)*
PuraDerm Gel is indicated for the hydration and management of partial and full thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, surgical wounds, and abrasions and burns associated with dermabrasion and laser resurfacing.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided below.

## 1. SUBMITTER

3-D Matrix, Inc.
250 First Ave., Suite 205
Needham, MA 02494

Contact Person: Lisa Spirio, PhD
Phone: 617-875-6204
Email: lisa@puramatrix.com

Prepared By: Stephen P. Rhodes, Streamline Regulatory,
stephen.rhodes@streamlineregulatory.com
Date Prepared: May 7, 2020

## 2. SUBJECT DEVICE

Name of Device: PuraDerm Gel
Common Name: Wound Dressing
Classification Regulation/Class: Unclassified
Product Code: FRO
Panel: General and Plastic Surgery

## 3. PREDICATE DEVICE

Predicate Devices: PuraDerm Gel (K143058) and Woun'Dres (K991202)

## 4. DEVICE DESCRIPTION

**Description**
PuraDerm Gel consists of a synthetic, peptide-based hydrogel material provided in a prefilled syringe. PuraDerm Gel is comprised of 2.5% (w/v) of a synthetic repeating peptide (acetyl-[arginyl-alanyl-aspartyl-alanyl]4-amide tetrahydrochloride in sterile water for injection. The peptide is synthesized by standard solid-phase chemistry with no raw materials of animal or cellular origin.

The PuraDerm Gel solution is sterile-filtered and filled into 5-ml syringes made of cyclo-olefin polymers with a high-density polyethylene plunger and a butyl rubber head cap and gasket. Each syringe is filled with either 1, 3, or 5 ml of gel.

PuraDerm Gel forms a three-dimensional hydrogel scaffold, which, at a basic structural level, is composed of a matrix of nanofibrils formed from individual peptide monomers. These fibrils are 10-20 nm in diameter and are interwoven to create an ordered structure with 50-100 nm pore

sizes. This woven network structure, or matrix barrier, is similar to the microarchitecture of endogenous extracellular matrix ("ECM").

The gel is delivered to the intended application site(s) via a polypropylene applicator nozzle tip. This same delivery system was previously cleared by FDA in K143058, and there have been no changes to the delivery system for PuraDerm Gel since K143058.

## 5. INDICATION FOR USE

PuraDerm Gel is indicated for the hydration and management of partial and full thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, surgical wounds, and abrasions and burns associated with dermabrasion and laser resurfacing.

## 6. SUBSTANTIAL EQUIVALENCE DISCUSSION

As shown in the table below, the technical characteristics of the PuraDerm Gel are identical to the predicate (K143058). Additionally, the Woun'Dres predicate (K991202) is provided for comparison of the indications for use.

**Table 1: Device Comparison Table**

| | **Proposed Device** | **Predicate Device** | **Predicate Device** |
|---|---|---|---|
| **510(k) Number** | K193085 | K143058 | K991202 |
| **Applicant** | 3-D Matrix | 3-D Matrix | Coloplast Corp |
| **Trade name** | PuraDerm Gel | PuraDerm Gel | Woun'Dres Collagen Hydrogel |
| **Classification Regulation** | Unclassified | Unclassified | Unclassified |
| **Product Code** | FRO | FRO | MGQ |
| **Indications for Use** | PuraDerm Gel is indicated for the hydration and management of partial and full thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, surgical wounds, and abrasions and burns associated with dermabrasion and laser resurfacing. | PuraDerm Gel is used for the management of partial and full thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds. | May be used for superficial wounds and abrasions and minor burns. Use under the supervision of health care professions for the local management of partial- and full-thickness wounds including pressure, and diabetic ulcers; lower extremity ulcers including those of venous, arterial and mixed etiology; surgical wounds; first- and second-degree burns including management of abrasions and burns associated with dermabrasion and laser resurfacing. |

| | **Proposed Device** | **Predicate Device** | **Predicate Device** |
|---|---|---|---|
| Contraindications | Do not use on patients with a known sensitivity to the gel or any of its components.<br><br>Do not use on third degree burns. | Do not use on patients with a known sensitivity to the gel or any of its components.<br><br>Do not use on third degree burns. | Do not use on third-degree burns. |
| Single use | Yes | Yes | No |
| Amount used | At physician's discretion, fill wound to the level of the surrounding skin | At physician's discretion, fill wound to the level of the surrounding skin | At physician's discretion, fill wound to the level of the surrounding skin |
| Capable of absorbing exudate | Yes (may be used for mild exudate) | Yes (may be used for mild exudate) | Yes (minimal to moderate exudate) |
| Duration of continuous wear | Recommended maximum of 7 days | Recommended maximum of 7 days | Minimum dressing change 3 times per week [2-3 day maximum continuous wear] |
| Sterilized | Yes | Yes | Unknown |
| Labeled sterile | Yes | Yes | No |
| Preservative free | Yes | Yes | No |
| Appearance | Clear, viscous gel | Clear, viscous gel | Clear amorphous gel |

The indications for use for PuraDerm Gel has the following modifications from the predicate K143058):

- "Used" has been replaced with "indicated" to more accurately reflect the indications.
- "Management" has been replaced with "hydration and management" to more completely describe the intended use of the hydrogel.
- "Abrasions and burns associated with dermabrasion and laser resurfacing" has been added to the indications for use. These additional indications were included in the predicate K991202 Coloplast Corporation's Woun'Dres Collagen Hydrogel, which was one of the predicate devices for the original PuraDerm Gel predicate (K143058).

The first two modifications to the predicate indications for use improve the accuracy of the indications and do not affect the intended use of the device. The additional indications of dermabrasion and laser resurfacing do not raise different questions of safety and effectiveness. In fact, the Woun'Dres predicate (K991202) for PuraDerm Gel (K143058) included these identical indications. Therefore, the modifications to the indications for use do not affect the intended use of the device, which is to hydrate and manage wounds.

Additionally, the technological characteristics of the new and predicate device are identical. There have been no design modifications to PuraDerm Gel since it was cleared in K143058.

## 7. PERFORMANCE DATA

Because there is no change to the device, source material, or manufacturing compared to the predicate K143058, the existing biocompatibility, sterilization, and shelf life information from K143058 fully applies. GLP pyrogenicity testing showed that the device is considered to be non-pyrogenic.

New performance testing was not necessary to support the additional indications or the updates to the IFU.

## 8. CONCLUSIONS

In conclusion, PuraDerm Gel is substantially equivalent to the predicate devices (K143058 and K991202).