October 8, 2021

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

Re: K210211
Trade/Device Name: PuraStat-OM
Regulatory Class: Unclassified
Product Code: OLR, MGQ
Dated: September 3, 2021
Received: September 7, 2021

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K210211

Device Name

PuraStat-OM

Indications for Use *(Describe)*
PuraStat-OM adheres to oral tissue and forms a protective barrier over the wound to prevent further irritation and contamination. It provides a moist wound environment required for optimal wound healing.

Manages pain of, for example:
- All types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa
- Canker sores and cold sores
- Irritation and traumatic ulcers such as those caused by various appliances such as braces, brackets, full and partial dentures and palatal expanders
- Soft tissue pain from orthodontics
- Aphthous ulcers
- Extraction site pain
- Oral mucositis and stomatitis (may be caused by chemotherapy or radiotherapy)

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.

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

1. SUBMITTER

3-D Matrix, Inc.
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Prepared By: Stephen P. Rhodes, Streamline Regulatory
stephen.rhodes@streamlineregulatory.com
Date Prepared: October 7, 2021

2. DEVICE

Name of Device: PuraStat-OM
Common Name: Wound and Burn Hydrogel Dressing w/Drug and/or Biologic
Classification Regulation: Unclassified
Regulatory Class: Unclassified
Product Code: MGQ
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: McMerlin Dental Company's SOCKIT!® Oral Hydrogel Wound Dressing (K063148)

Reference Device: 3-D Matrix, Inc. PuraDerm Gel (K143058)

4. DEVICE DESCRIPTION

PuraStat-OM is a sterile gel composed of a synthetic peptide and sterile water for injection. It is provided as a prefilled syringe (2.5% peptide content) ready for use as an oral hydrogel wound dressing with the sterile application nozzle. The gel's primary mode of action is that it adheres to the wound surface, conforms to the contours of the wound, and protects the wound from contamination and irritation by forming a protective barrier that is similar to the natural mucosa. It also creates and maintains a moist wound environment, which is necessary for the natural healing process.

PuraStat-OM is completely non-animal and non-plant derived and contains no drugs or biologics that might present a risk of allergic reaction or skin irritation.

Exposure to physiological fluids such as blood causes the peptide solution to quickly form a transparent gel without expansion in volume.

5. INDICATIONS FOR USE

PuraStat-OM adheres to oral tissue and forms a protective barrier over the wound to prevent further irritation and contamination. It provides a moist wound environment required for optimal wound healing.

Manages pain of, for example:

- All types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa
- Canker sores and cold sores
- Irritation and traumatic ulcers such as those caused by various appliances such as braces, brackets, full and partial dentures and palatal expanders
- Soft tissue pain from orthodontics
- Aphthous ulcers
- Extraction site pain
- Oral mucositis and stomatitis (may be caused by chemotherapy or radiotherapy)

The intended use of the subject device is identical to the predicate device's intended use. The indications for use of the subject device are identical to the predicate's indications for use, with the exception that:

- the predicate device is indicated for "irritation and pain following tooth sealing and prophylaxis," and the subject device does not include this indication; and
- the predicate device does not have the following statement found in the subject device: *"... (may be caused by chemotherapy or radiotherapy)."* The indications for use for the subject PuraStat-OM and predicate device include "oral mucositis and stomatitis," with the difference being that the subject device includes potential causes for the mucositis and stomatitis, i.e. chemotherapy or radiotherapy. There are several oral hydrogel wound dressings that include chemotherapy and radiotherapy as examples of causes for oral mucositis and stomatitis.

Thus, PuraStat-OM does not have a new intended use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The similarities and differences in technological characteristics between the subject device (PuraStat-OM), predicate device (SockIt!® Gel – K063148), and the reference device (PuraDerm Gel - K143058) are summarized below.

PuraStat-OM and the predicate SockIt!® Oral Hydrogel Wound Dressing (K063148) are both intended to manage the pain in oral wounds by adhering to oral tissue and forming a protective barrier between the wound and further irritation. The gels provide a moist wound environment required for optimal wound healing.

Both are clear, viscous hydrogels that are safe. The primary mode of action is that they adhere to the wound surface, conform to the contours of the wound, and protect the wound from contamination and irritation by forming a protective barrier that is similar to natural mucosa.

The PuraStat-OM 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. The device is terminally sterilized, and the resorbable gel is delivered to the intended application site(s) via a polypropylene applicator nozzle tip.

SockIt!® Gel is not sterilized and is provided in a prefilled syringe. The viscous gel is delivered to the intended application site(s) via an applicator nozzle.

Both devices need to deliver the gel via a syringe, and both need to function as a temporary wound covering.

In terms of technological differences, PuraStat-OM consists of a synthetic peptide-based hydrogel material provided in a prefilled syringe. PuraStat-OM 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 predicate SockIt!® Gel contains mannose polysaccharides from Aloe vera, xylitol and a tiny number of essential oils of cinnamon, clove, and thyme. As packaged, PuraStat-OM has a pH of 2.0 and SockIt!® has a pH of 6.8. However, after 10 minutes in human saliva and human blood, the pH of PuraStat-OM changed to 6.2 and 6.0, respectively, and the pH of SockIt!® increased to 7.7 and 7.6, respectively. Both devices are hydrogels designed to be used as a barrier to contamination or irritation of oral mucosal surfaces. The differences in the material compositions of the two devices raises no different questions of safety and effectiveness. Additionally, the difference in material between the devices was addressed by a side-by-side comparison of the devices in bench studies summarized in Section 7 below.

Overall, the differences in technological characteristics of the subject and predicate devices do not raise any different questions of safety and effectiveness.

Lastly, the subject PuraStat-OM is the identical product cleared as the PuraDerm Gel reference device (K140358) although for different indications.

7. PERFORMANCE DATA

The substantial equivalence evaluation of PuraStat-OM and SockIt!® Gel was supported by non-clinical performance including GLP biocompatibility testing, as per ISO 10993-1 and consistent with FDA Guidance, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and bench testing.

PuraStat-OM is classified as a surface device, with breached or compromised surface contact and prolonged contact duration (24 hours to 30 days). Biocompatibility testing included:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subchronic / Subacute Toxicity
- Implantation

- Material-Mediated Pyrogenicity

These tests provide confirmation that the device does not give rise to toxic effects at the cellular, local or systemic level. The presence of the device in tissues leads to a normal inflammatory response characterized by a granulomatous foreign body reaction, resolving comparatively rapidly to capsular fibrosis. The device is identical to the reference device, PuraDerm Gel, cleared as a wound dressing in K143058.

The following bench tests were conducted on PuraStat-OM and the SockIt!® Gel predicate:

- Complex Modulus, Simulated Body Fluid
- Complex Viscosity, Simulated Body Fluid
- Viscosity
- Injection Force
- pH

The complex modulus and complex viscosity of the subject device are greater than the predicate device, which shows that PuraStat-OM will form a physical barrier for the wound that is as at least as effective as the predicate device due to its increased physical strength. The viscosity of PuraStat-OM was lower than that of SockIt!® Gel, making it easier to inject the product onto the wound site. This result was confirmed by the side-by-side injection for testing, which demonstrated that PuraStat-OM required less force than the predicate Sockit!® Gel.

After contact for 10 minutes with human saliva and human blood, the pH of PuraStat-OM was found to be 6.2 and 6.0, respectively, which is comparable to the 7.7 and 7.6 pH, respectively of SockIt!®.

Overall, compared to Sockit!® Gel, PuraStat-OM is a stronger material at a steady-state after contacting a simulated bodily fluid, but it shows lower viscosity at high shear rates and requires less injection force to use than Sockit!® Gel.

8. CONCLUSIONS

The subject PuraStat-OM has the same intended use and similar indications as the predicate SockIt!® Gel (K063148). The removal of irritation and pain following tooth scaling and prophylaxis and the addition of examples of causes of oral mucositis and stomatitis, i.e., chemotherapy or radiotherapy) do not constitute a new intended use.

There are similar technological characteristics between the subject PuraStat-OM and the predicate SockIt!® Gel. The differences in technological characteristics do not raise any different questions of safety or effectiveness.

PuraStat-OM is identical in material, formulation, and manufacturing to the reference device, the PuraDerm Gel (K143058).