April 1, 2022

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

Re: K213552
Trade/Device Name: PuraStat-RM
Regulatory Class: Unclassified
Product Code: PHN
Dated: November 5, 2021
Received: November 8, 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,

Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K213552

Device Name
PuraStat-RM

Indications for Use *(Describe)*
PuraStat-RM is indicated for the symptomatic management of rectal mucositis, such as radiation proctitis that 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-RM is provided below.

1. SUBMITTER

3-D Matrix, Inc.
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Contact Person: Lisa Spirio, PhD
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Prepared By: Stephen P. Rhodes, Streamline Regulatory
stephen.rhodes@streamlineregulatory.com
Date Prepared: March 31, 2022

2. DEVICE

Name of Device: PuraStat-RM
Common Name: Mucoadhesive Application for the Protective Coating of the Rectal Mucosa
Classification Regulation: Unclassified
Regulatory Class: Unclassified
Product Code: PHN
Panel: Gastroenterology / Urology

3. PREDICATE DEVICE

Predicate Devices: Access Pharmaceuticals, Inc.'s ProctiGard (K140558) and 3-D Matrix Inc.'s PuraStat-OM (K210211)

Reference Device: 3-D Matrix, Inc.'s PuraStat-GI (K210098)

4. DEVICE DESCRIPTION

PuraStat-RM 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 a mucoadhesive hydrogel that provides a protective barrier over rectal mucosa. The gel is delivered to the intended application site(s) via a commercially available endoscopic catheter that is attached to the gel syringe via the polypropylene adapter.

PuraStat-RM 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-RM is indicated for the symptomatic management of rectal mucositis, such as radiation proctitis that 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 for the subject PuraStat-RM are the same as the predicate ProctiGard (K140558), with the difference being that the subject device includes radiation proctitis that may be caused by chemotherapy or radiotherapy as an example of rectal mucositis. Thus, PuraStat-RM does not have a new intended use. The subject and predicate ProctiGard are both gels that are intended to provide a protective layer over rectal mucosa.

The subject PuraStat-RM has the same intended use as the predicate PuraStat-OM (K210211). Both devices are mucoadhesive gels that provide a protective layer over mucosa. The mode of action of PuraStat-RM is achieved in an identical manner to that of PuraStat-OM, i.e., through the formation of a protective layer over the mucosa (over the rectal mucosa rather than the oral mucosa).

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

PuraStat-RM and the predicate ProctiGard (K140558) are both mucoadhesive gels that provide a protective coating over the rectal mucosa.

The PuraStat-RM 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.

The predicate ProctiGard is also a sterile mucoadhesive formulation that results in the formation of a protective coating over the rectal mucosa.

Both devices need to deliver the gel via a syringe and both need to function as a temporary space-occupying gel stent.

In terms of technological differences, PuraStat-RM consists of a synthetic peptide-based hydrogel material provided in a prefilled syringe. PuraStat-RM 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 ProctiGard is a mixture of film-forming polymers. Both devices are hydrogels designed to form a protective layer over rectal mucosa. The differences in the material compositions of the two devices raises no new questions of safety and effectiveness.

PuraStat-RM and the predicate PuraStat-OM (K210211) are identical devices, both are mucoadhesive gels that provide a protective coating over mucosa.

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

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

7. PERFORMANCE DATA

The substantial equivalence evaluation of PuraStat-RM and ProctiGard 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-RM 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 predicate device PuraStat-OM (K210211) and reference device PuraStat-GI (K210098).

The following bench tests were conducted on PuraStat-RM:

- Storage Modulus, Simulated Body Fluid
- Loss Modulus, Simulated Body Fluid
- Complex Modulus, Simulated Body Fluid
- Complex Viscosity, Simulated Body Fluid
- Injection Force
- Ex-vivo Mucoadhesive Properties
- Adapter Functional Testing

The following clinical data was provided on the use of PuraStat-RM and to demonstrate substantial equivalence:

The safety and effectiveness of the use of PuraStat-RM as a hemostat to control rectal bleeding after radiation proctopathy (RP) was evaluated in the United Kingdom, in a prospective, consecutive, open-label, single center case series between June 2018 and September 20191. Consecutive patients attending pelvic radiation disease clinic with severe refractory RP were offered treatment with PuraStat-RM. Twenty-one patients were treated ((18 men; 17 prostate, 2 vaginal, 2 rectal; median age 76 years (range 47–84)) with a median of three treatments. Ten were on antithrombotics, 1 had thrombocytopenia and 13 had anaemia at baseline. PuraStat-RM was applied endoscopically at four weekly intervals, with more as required. The median time from first PuraStat-RM treatment to final follow-up information is 12 months (range 3–18). No patients were lost to follow-up. For those patients >12 months beyond their first PuraStat-RM treatment, only one has had recurrence of significant bleeding. Of the 16 patients who have been seen in clinic following PuraStat-RM treatment, 14 have had a marked improvement in their bleeding in terms of volume and frequency, both subjectively (patient-reported in clinic) and according to 7-

day patient-reported bleeding diaries. Median number of PuraStat-RM treatments was 3 (range 2–7). Median PuraStat-RM amount used was 5 mL (range 3–5 mL). There was an improvement in rectal bleeding as determined by 7-day patient-reported bleeding diaries and physician-reported rectal bleeding score. Number of episodes of rectal bleeding into the toilet bowl reduced from a median of 4.5 (range 0–27) to 2 (range 0–16) from the 7 days prior to the first treatment to the 7 days prior to the third treatment.

8. CONCLUSIONS

The subject PuraStat-RM has the same intended use and similar indications as the predicates ProctiGard (K140558) and PuraStat-OM (K210211).

There are similar technological characteristics between the subject PuraStat-OM and the predicate ProctiGard (K140558). The differences in technological characteristics do not raise any different questions of safety or effectiveness. PuraStat-RM is identical in material, formulation and manufacturing to the predicate PuraStat-OM (K210211).

PuraStat-RM is identical in material, formulation, and manufacturing to the reference device, the PuraStat-GI (K210098).