August 3, 2026

3-D Matrix, Inc.
Alan Miskewicz
RAQA Director
1234 Chestnut St., Suite 205
Newton, Massachusetts 02464

Re: K261504
Trade/Device Name: PuraStat-RM
Regulatory Class: Unclassified
Product Code: PHN
Dated: May 6, 2026
Received: May 6, 2026

Dear Alan Miskewicz:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
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)*
K261504

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.

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

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510(k) SUMMARY

K261504

1. SUBMITTER

3-D Matrix Inc.
1234 Chestnut Street – Suite 205
Newton -– MA 02464
USA

Contact Person : Alan MISKEWICZ
RAQA Director - 3-D Matrix, Inc.
Phone: 617-291-0586
Email: amiskewicz@3dmatrix.com
Date Prepared: July 29th, 2026

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 DEVICES

Primary predicate: 3-D Matrix Inc. PuraStat-RM (K213552)

Additional predicates: 3-D Matrix Europe SAS PuraStat (K242634, K253923)

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 either with the separately packaged adapter and a commercially available luer lock endoscopic catheter, or with a direct connect endoscopic catheter, to deliver the gel. Adapter and endoscopic catheters are sold separately.

PuraStat-RM is completely non-animal and non-plant derived and contains no preservatives 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 intended to be used for the symptomatic management of rectal mucositis, such as radiation proctitis that may be caused by chemotherapy or radiotherapy.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject PuraStat-RM is substantially equivalent to the originally cleared device (K213552) and to additional cleared devices (K242634, K253923) representing alternative configurations of the same technology.
The subject device includes cumulative non-significant changes that are consistent with those previously cleared for the predicate devices. These variations do not affect the technological principles, mode of action, or performance of the device.
Performance data, including verification and validation activities, demonstrate that the subject device performs as intended and is as safe and effective as the predicate devices.

The final product specifications are equivalent.

PuraStat-RM is comprised of a synthetic repeating 16-amino acid (RADA-16) oligopeptide in sterile water for injection. In the presence of physiological pH (blood or tissue), the peptides assemble into a scaffold structure that results in the formation of a protective coating over the rectal mucosa. The solution is 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 commercially available adapter connected to a commercially available catheter, or with a direct connect endoscopic catheter, to deliver the gel. Adapter and endoscopic catheters are sold separately. The device is delivered endoscopically via a catheter to the patient.

7. PERFORMANCE DATA

The subject PuraStat-RM is substantially equivalent to the originally cleared device (K213552) and to additional cleared devices (K242634, K253923) representing alternative configurations of the same technology.

The subject device has the same intended use and indications for use as the predicate devices.

An evaluation of equivalence was conducted taking into account cumulative non-significant changes. The performance data provided in this submission, including bench and biocompatibility testing, support this evaluation.

The results demonstrate that the subject device performs as intended and that any differences in technological characteristics do not raise new questions of safety and effectiveness.

8. CONCLUSIONS

The subject PuraStat-RM is substantially equivalent to the original PuraStat-RM (K213552) and to the Predicate device 3-D Matrix Europe SAS PuraStat (K242634, K253923) in intended use, raw materials, specifications, chemical composition and performance. All those products aim to achieve hemostasis for the same indications through the same mechanism and contact the same human tissues and fluids. Concerning the differences between the subject device and the original PuraStat-RM (K213552), all are addressed using proven methods, and all test results meet the applicable requirements, as demonstrated by comparison with the predicate device, 3-D Matrix Europe SAS PuraStat (K242634, K253923), already cleared.

In conclusion, PuraStat-RM is substantially equivalent to the predicates.