January 7, 2026

3-D Matrix Europe SAS
Audrey Vion
Regulatory Affairs & Quality Assurance Manager
11 Chemin Des Petites Brosses
2nd Floor
Caluire Et Cuire, Rhone 69300
France

Re: K253923
Trade/Device Name: PuraStat
Regulatory Class: Unclassified
Product Code: PHN
Dated: December 8, 2025
Received: December 8, 2025

Dear Audrey Vion:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 C. Lee, Ph.D., M.B.A.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253923

Please provide the device trade name(s).

PuraStat

Please provide your Indications for Use below.

Purastat is indicated for the symptomatic management of rectal mucositis, such as radiation proctitis that may be caused by chemotherapy or radiotherapy.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided below for this Special 510(k) (K253923).

1. SUBMITTER

3-D Matrix Europe SAS
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69300 Caluire et Cuire - FRANCE

Contact Person: Audrey VION
Phone: +33 (0) 627 635 514
Email: avion@puramatrix.com

Date Prepared: January 06, 2026

2. DEVICE

Name of Device: PuraStat

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 Device: PuraStat (3-D Matrix Europe SAS) - K242634

4. DEVICE DESCRIPTION

PuraStat 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-filled syringe via the polypropylene adapter also commercially available.

PuraStat 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 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 modified PuraStat is identical in material, formulation, and manufacturing steps except for the additional sterilization method and minor differences in the packaging and syringe components.

7. PERFORMANCE DATA

The determination of substantial equivalence is based on an assessment of non-clinical performance data. To verify that the device design modifications meet the functional and performance requirements, PuraStat underwent the following performance testing.
The tests were performed on the subject device using the same method as the predicate device, and acceptance criteria.

- Gamma Sterilization Validation / ISO 11137
- Product performance
- Packaging Validation / ISO 11607
- Product stability
- Biocompatibility / ISO 10993-1

Additional performance testing has been conducted to assess the changes introduced:

- EtO Sterilization Validation / ISO 11135
- EO/ECH residual analysis / ISO 10993-7
- Equivalence in mechanical properties of syringe component by comparing predicate and subject device components.

8. CONCLUSION

Technological characteristics between the predicate PuraStat (K242634) and the subject device are identical, with the exception of the final sterilization and minor differences in the packaging and syringe components. These differences do not raise any questions of safety or effectiveness. PuraStat is identical in material, formulation and manufacturing, and so final product specification to the predicate PuraStat (K242634).

In conclusion, 3-D Matrix Europe SAS believes that the modified PuraStat is substantially equivalent to the original PuraStat (K242634).