August 03, 2026

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

Re: K261503
Trade/Device Name: PuraStat GI
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
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,

TEK N. LAMICHHANE
-S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261503

Device Name
PuraStat GI

Indications for Use *(Describe)*
PuraStat is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary non-variceal gastrointestinal (GI) bleeding. PuraStat is not indicated for arterial Forrest 1a bleeding.

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

K261503

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: June 11, 2026

2. DEVICE

Name of Device: PuraStat GI
Common Name: Hemostatic device for intraluminal gastrointestinal use
Classification Regulation: 21 CFR 878.4456
Regulatory Class: II
Product Code: QAU
Panel: General & Plastic Surgery

3. PREDICATE DEVICES

Primary Predicate Device: 3-D Matrix Europe SAS PuraStat (K242250, K253924)

4. DEVICE DESCRIPTION

PuraStat GI is a sterile gel composed of 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 GI 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. PuraStat GI achieves hemostatic effects by forming a hydrogel matrix barrier that blocks the flow of blood at the site of application.

5. INDICATIONS FOR USE

PuraStat GI is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary non-variceal gastrointestinal (GI) bleeding. PuraStat GI is not indicated for arterial Forrest 1a bleeding.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject PuraStat GI is substantially equivalent to the primary predicate PuraStat (K242250, K253924) 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 device.

	Subject Device	Primary Predicate	Difference
Device and Manufacturer	**PuraStat GI** **3-D MATRIX Inc.**	**PuraStat** **3-D MATRIX EUROPE SAS**	/
510k N°	**K261503**	**K242250 & K253924**	/
Intended use	PuraStat GI is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary gastrointestinal (GI) bleeding.	3-D MATRIX Europe SAS PuraStat is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary gastrointestinal (GI) bleeding.	**Identical**
Indications for use	PuraStat GI is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary non-variceal gastrointestinal (GI) bleeding. PuraStat is not indicated for arterial Forrest 1a bleeding.	3-D MATRIX Europe SAS PuraStat is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary non-variceal gastrointestinal (GI) bleeding. PuraStat is not indicated for arterial Forrest 1a bleeding.	**Identical**
Regulation	878.4456	878.4456	**Identical**
Product code	QAU	QAU	**Identical**
Class	II	II	**Identical**

	Technological Characteristics		
	Subject Device	**Primary Predicate**	**Difference**
Device Design Description	3-D MATRIX Inc. PuraStat is a synthetic haemostatic product supplied as a prefilled syringe containing a clear aqueous peptide solution. PuraStat GI is made of synthetic, absorbable peptides that form a hydrogel when applied. These peptides are designed to self-assemble into a structured network under physiological conditions. This process is driven by interactions between different parts of the peptide molecules, allowing them to organize into a gel that helps control bleeding. The self-assembly is promoted by conditions typically found in the body, such as neutral pH and the presence of common ions.	3-D MATRIX Europe SAS PuraStat is a synthetic haemostatic product supplied as a prefilled syringe containing a clear aqueous peptide solution. PuraStat is made of synthetic, absorbable peptides that form a hydrogel when applied. These peptides are designed to self-assemble into a structured network under physiological conditions. This process is driven by interactions between different parts of the peptide molecules, allowing them to organize into a gel that helps control bleeding. The self-assembly is promoted by conditions typically found in the body, such as neutral pH and the presence of common ions.	**Identical**
Chemical description	3-D Matrix Inc. PuraStat GI consists of a 2.5% solution of a synthetic peptide in sterile water for injection. The peptide is manufactured using standard chemical synthesis methods and does not contain any materials of animal or biological origin.	3-D Matrix Europe SAS PuraStat consists of a 2.5% solution of a synthetic peptide in sterile water for injection. The peptide is manufactured using standard chemical synthesis methods and does not contain any materials of animal or biological origin.	**Identical**
Materials	Synthetic peptide hydrogel	Synthetic peptide hydrogel	**Identical**
Absorbable	Resorbed within 30 days	Resorbed within 30 days	**Identical**
Appearance	Clear, viscous gel	Clear, viscous gel	**Identical**
Product range	Three volumes are available: 1ml, 3ml, 5ml	Three volumes are available: 1ml, 3ml, 5ml	**Identical**

	Technological Characteristics		
	Subject Device	**Primary Predicate**	**Difference**
Principle of Operations	The product is a transparent aqueous peptide solution that, when applied to a bleeding site, rapidly forms a hydrogel barrier. This barrier helps control bleeding by covering the affected area and supporting the body's natural coagulation process. Its transparency allows clear visualization of the treatment site during use. Upon contact with physiological fluids, such as blood, the solution undergoes a change that triggers the peptides to self-assemble into a gel. This gel adheres to the tissue and forms a protective layer over the bleeding surface, contributing to effective hemostasis. Any remaining product is gradually absorbed by the body over time, although small amounts may persist for an extended period.	The product is a transparent aqueous peptide solution that, when applied to a bleeding site, rapidly forms a hydrogel barrier. This barrier helps control bleeding by covering the affected area and supporting the body's natural coagulation process. Its transparency allows clear visualization of the treatment site during use. Upon contact with physiological fluids, such as blood, the solution undergoes a change that triggers the peptides to self-assemble into a gel. This gel adheres to the tissue and forms a protective layer over the bleeding surface, contributing to effective hemostasis. Any remaining product is gradually absorbed by the body over time, although small amounts may persist for an extended period.	**Identical**
Single use?	Yes	Yes	**Identical**
Provided sterile?	Yes	Yes	**Identical**
Sterilization method	**Contract Sterilizers #1:** Gamma radiation between 17,5 kGy and 25 kGy of the device followed by a terminal EtO sterilization for final packaging sterilization **Contract Sterilizer #2:** Terminal Gamma radiation between 17,5 kGy and 25 kGy of the finished packaged device.	**Contract Sterilizers #1 (K253924):** Gamma radiation between 17,5 kGy and 25 kGy of the device followed by a terminal EtO sterilization for final packaging sterilization **Contract Sterilizer #2 (K242250):** Terminal Gamma radiation between 17,5 kGy and 25 kGy of the finished packaged device.	**Identical**
Shelf life	3 years	3 years	**Identical**
User population	PuraStat GI must be used by healthcare professionals (e.g surgeons, endoscopists, nurses, etc.)	3-D MATRIX Europe SAS PuraStat must be used by healthcare professionals (e.g surgeons, endoscopists, nurses, etc.)	**Identical**
How the gel is delivered	Gel in a syringe, connected to catheter and delivered endoscopically. The gel solution is applied as close as possible to the bleeding point.	Gel in a syringe, connected to catheter and delivered endoscopically. The gel solution is applied as close as possible to the bleeding point.	**Identical**

The final product specifications are equivalent.

PuraStat GI is comprised of a synthetic repeating 16-amino acid (RADA-16) oligopeptide in sterile water for injection. In the presence of a bleeding wound, the peptides assemble into a scaffold structure that forms a mechanical barrier over the bleeding site. 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 GI is substantially equivalent to the primary predicate PuraStat (K242250, K253924) representing alternative configurations of the same technology.

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

The determination of substantial equivalence is based on an assessment of non-clinical performance data.

PuraStat underwent the following performance testing.
- Gamma Sterilization Validation / ISO 11137
- Product performance
- Packaging Validation / ISO 11607
- Product stability over shelf life
- Biocompatibility / ISO 10993-1

The tests were performed on the subject device using the same methods, and acceptance criteria used for the primary predicate device.

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.

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 GI is substantially equivalent to the primary predicate device 3-D Matrix Europe SAS PuraStat (K242250, K253924) 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.

PuraStat complies with the special controls for a hemostatic device for intraluminal gastrointestinal internal use.

In conclusion, PuraStat GI is substantially equivalent to the primary predicate.