February 28, 2023

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

Re: K222481
Trade/Device Name: PuraStat
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
Dated: February 15, 2023
Received: February 15, 2023

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.02.27 22:27:19 -05'00'

for Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K222481

Device Name
PuraStat

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

1. SUBMITTER

3-D Matrix, Inc.
1234 Chestnut St., Suite 205
Newton, MA 02464

Contact Person: Lisa Spirio, PhD
Phone: 617-875-6204
Email: lisa@3dmatrix.com

Date Prepared: February 28, 2023

2. DEVICE

Name of Device: PuraStat
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 DEVICE

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

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 hemostat. 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 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 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 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device is the identical product as the PuraStat-GI predicate (K210098).

PuraStat 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 hemostatic 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 adapter connect to a commercially available catheter. The device is delivered endoscopically via a catheter to the bleeding site.

7. PERFORMANCE DATA

The subject device is identical to the predicate device. The intended use of the subject device is identical to the intended use of the predicate device. The indications for use of the subject device are identical to the predicate's indications for use, with the exception that the subject device has the following statement not found in the predicate device: "… and for primary non-variceal gastrointestinal (GI) bleeding."

Because the subject device is identical to the predicate device and has the same intended use, the bench testing, animal testing and biocompatibility testing provided in the predicate device (K210098) was referenced for the subject device.

The additional indication for primary non-variceal gastrointestinal (GI) bleeding for the subject device was addressed by clinical data in an OUS study reported in the literature.

Branchi et al Study (2021) *

The safety and effectiveness of the use of PuraStat as a primary hemostat to control primary bleeding in patients with acute non-variceal gastrointestinal bleeding (upper and lower) was evaluated in 111 patients in a prospective, consecutive open-label, multi-center study between July 2017 and December 2018 at 15 endoscopy departments in Germany. The effectiveness of PuraStat was assessed during the procedure, at 3 days and 1 week after application.

The primary endpoint was the achievement of hemostasis during the procedure with PuraStat (procedure success). Secondary end points were the prevention of rebleeding (defined as therapy success), the documentation of risk and side effect profiles of PuraStat. Rebleeding was defined as the presence of clinical signs of gastrointestinal bleeding (hematemesis, melena, hematochezia) in association with cardiovascular instability or Hemoglobin drop. A stable clinical condition without signs of rebleeding assessed at 3 and 7 days after the application of PuraStat was defined as therapy success.

Inclusion criteria were age > 18 years, acute upper or lower gastrointestinal bleeding including active bleeding and lesions with signs of recent hemorrhage such as visible vessels (Forrest Classification IIA or adherent clots or pigmented spots (Forrest Classification IIB) according to the Forrest classification. Adverse events were recorded for 30 days post procedure.

i. Demographics and Patient Accounting

A total of 111 patients with gastrointestinal bleeding were included and treated with PuraStat; 68 were men and 43 were women. The bleeding activity was in most cases classified as oozing bleeding (76/111, 69%), in seven cases spurting hemorrhage (6%), in 16 cases a visible vessel (14%) and in 6 cases each (5%) an adherent clot or hematin on the ground of a lesion were observed. In all seven patients with spurting bleeding, PuraStat was applied as a secondary therapy to standard techniques, thus utilizing a combination of submucosal injection, hemoclips, over-the-scope clips (OTSC) and gel to reach final hemostasis. After endoscopy therapy, none of these patients required surgery which was an overwhelming positive outcome for these patients.

No patients were lost to follow-up.

After primary application of PuraStat, initial hemostatic success was achieved in 94% of patients (74/79, 95% CI 88–99%), and in 75% of the patients when used as a secondary hemostatic product, following failure of established techniques (24/32, 95% CI 59–91%). The therapeutic success rates (absence of rebleeding) after 3 and 7 days were 91% and 87% after primary use, and 87% and 81% in all study patients. Overall rebleeding rate at 30-day follow-up was 16% (18/111). In the 5 patients who finally required surgery (4.5%), PuraStat allowed temporary hemostasis and stabilization.

No adverse events due to application of PuraStat or technical failures were reported.

The largest proportion of patients in the study were patients with active oozing bleeding, in whom typically a rebleeding rate of up to 50% is reported in the literature; however, in this study we found a rebleeding rate of 12% at 7 days and of 16% at 30 days in our whole patients' collective. After primary application of PuraStat, initial hemostatic success was achieved in 94% of patients (74/79, 95% CI 88–99%). The therapeutic success rates (absence of rebleeding) after 3 and 7 days were 91% and 87% after primary use. PuraStat was safely applied and administered without complications as a primary or secondary therapy.

* Branchi et al. *PuraStat in gastrointestinal bleeding: results of a prospective multicentre observational pilot study*. Surgical Endoscopy. 2021 June 15: 9 Feb; 7(1): 155–162.

8. CONCLUSIONS

The intended use of the subject device is identical to the predicate device's intended use. The indications for use for the subject PuraStat are modifications of the predicate device, with the difference being that the subject device has the additional indication of primary non-variceal gastrointestinal (GI) bleeding and the additional clarification that PuraStat is not indicated for arterial Forrest 1a bleeding. The addition of non-variceal primary bleeding does not change the intended use of hemostasis. Thus, PuraStat does not have a new intended use. The subject device is the identical product as the PuraStat-GI predicate (K210098).

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

In conclusion, PuraStat is substantially equivalent to the predicate PuraStat-GI (K210098).