June 25, 2021

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

Re: K210098
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: January 13, 2021
Received: January 14, 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,

Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210098

Device Name
PuraStat-GI

Indications for Use *(Describe)*
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.

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.
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Prepared By: Stephen P. Rhodes, Streamline Regulatory,
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Date Prepared: January 6, 2021

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 DEVICE

Predicate Device: Wilson-Cook Medical, Inc.'s Hemospray® Endoscopic Hemostat (DEN170015)

Reference Device: 3-D Matrix, Inc.'s PuraDerm Gel (K143058)

4. DEVICE DESCRIPTION

PuraStat-GI 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-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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The similarities and differences in technological characteristics between the subject device (PuraStat-GI), predicate device (Hemospray® Endoscopic Hemostat – DEN 170015), and the reference device (PuraDerm Gel - K143058) are summarized below.

PuraStat-GI and the predicate Hemospray® are hemostasis devices that are delivered endoscopically via a catheter to the bleeding site.

The PuraStat-GI 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 an endoscopic catheter attached to the syringe with the polypropylene adapter.

For the predicate Hemospray®, the hemostatic agent is bentonite powder, a naturally sourced aluminum phyllosilicate clay. When Hemospray® comes into contact with an active bleeding site, the powder absorbs water, then forms a mechanical barrier over the bleeding site. The delivery system is an endoscopic accessory used for spraying the powder onto the bleeding surface. The delivery device consists of a 220cm polyethylene application catheter, a handle with a pressurized CO2 cartridge, and a powder chamber containing the Hemospray® material. The material is propelled through the application catheter by the release of CO2 from the cartridge located in the device handle.

In terms of technological differences, PuraStat-GI consists of a synthetic peptide-based hydrogel material provided in a prefilled syringe. PuraStat-GI 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 Hemospray® consists of bentonite powder. Both devices are designed to be used as a physical barrier to control gastrointestinal bleeding. The differences in the material compositions of the two devices raise no different questions of safety and effectiveness. Additionally, the difference in material between the devices was addressed by a side-by-side comparison of the devices in bench testing, which showed PuraStat-GI to have substantially equivalent mechanical properties. The differences in material between the devices were also addressed in a side-by-side comparison of the devices in a porcine animal model that evaluated hemostasis and re-bleeding rates. The difference in the material did not impact the safety and effectiveness of PuraStat-GI when compared to the Hemospray® predicate in a porcine animal model. The safety and effectiveness of the use of PuraStat-GI in gastrointestinal bleeding was also evaluated in three clinical studies. PuraStat-GI was a safe and effective hemostat for GI bleeding in the 223 patients that received it.

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

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

7. PERFORMANCE DATA

The difference in material between the devices was addressed by a side-by-side comparison of PuraStat-GI and Hemospray® in the following bench tests:

The following bench tests were conducted on PuraStat-GI and Hemospray® predicate:

- Complex Modulus
- Complex Viscosity
- Complex Modulus, Simulated Body Fluid
- Complex Viscosity, Simulated Body Fluid
- Injection Force
- Ex-vivo mucoadhesive properties

The PuraStat-GI syringe-adapter underwent Leakage by Pressure Decay, Subatmospheric-pressure Air Leakage, Stress Cracking, Resistance to Separation from Axial Load, Resistance to Separation from Unscrewing, and Resistance to Overriding testing per the methods in ISO 80369. The PuraStat-GI syringe-adapter is demonstrated to deliver PuraStat-GI reliably and safely to the bleeding site.

The difference in material between the devices was addressed by a side-by-side comparison of the devices in a GLP gastrointestinal mucosal defect study in a porcine model. The number of material administrations required and total elapsed time to hemostasis was comparable between Cook Hemospray® and PuraStat-GI. The incidence of rebleeding was comparable between Cook Hemospray® and PuraStat-GI, but PuraStat-GI had a favorable incidence of rebleeding in the upper GI. The difference in the material did not impact the safety and effectiveness of PuraStat-GI compared to the Hemospray® predicate.

To supplement the animal testing, we are providing the results of three clinical studies of the use of PuraStat® that have been reported in the literature on the performance of PuraStat®.

The safety and effectiveness of the use of PuraStat-GI in endoscopic gastrointestinal bleeding was evaluated in three clinical studies. PuraStat-GI was studied in 223 patients undergoing endoscopic GI procedures. The success rate of hemostasis, the delayed bleed rate / re-bleed rate, and mortality are provided in the table below.

Table: PuraStat® Clinical Results

Study	N (patients)	Hemostasis (%)	Delayed bleed Rate[1] (%)	Re-bleed Rate[2] (%)	Mortality (%)
Subramaniam (2019)	100	75	3	n/a	0
de Nucci (2020)	77	90	n/a	10	0
Subramaniam (2020)	46	92.6	4.3	n/a	0

[1]Delayed bleed rate following endoscopic resection, within 30 days
[2]Re-bleed rate following acute gastrointestinal bleeding, within 7 days

PuraStat-GI was shown to be an effective hemostat for GI bleeding. There were no adverse events related to the use of PuraStat-GI in the 223 patients that received it.

8. CONCLUSIONS

The subject PuraStat-GI has the same intended use and similar indications for use at the predicate Hemospray® Endoscopic Hemostat (DEN170015). Both devices are used endoscopically and are applied to gastrointestinal bleeding surfaces to provide hemostasis. Both devices form a mechanical barrier over the bleeding site.

The indications for use for the subject are a subset of the predicate device, with the difference being that the subject device is indicated for mild or moderate bleeding. Thus, PuraStat-GI does not have a new intended use.

The subject device is the identical product as the PuraDerm reference device (K143058). The biocompatibility testing and product characterization studies performed on the PuraDerm reference device apply to PuraStat-GI.

In conclusion, PuraStat-GI is substantially equivalent to the predicate Hemospray® Endoscopic Hemostat (DEN170015).