August 27, 2021

RevMedx, Inc.
Amy Pointer
Director of RA/QA
25999 SW Canyon Creek Road, Suite C
Wilsonville, Oregon 97070

Re: K210676
Trade/Device Name: XSTAT 30 Pouch
Regulation Number: 21 CFR 878.4452
Regulation Name: Nonabsorbable Expandable Hemostatic Sponge For Temporary Internal Use
Regulatory Class: Class II
Product Code: PGZ
Dated: July 26, 2021
Received: July 29, 2021

Dear Ms. Pointer:

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,

for Deborah Fellhauer, RN, BSN, CQIA
Acting 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)*
K210676

Device Name
XSTAT 30 Pouch

Indications for Use *(Describe)*

XSTAT 30 Pouch is a hemostatic device for the control of severe, life-threatening bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents.

XSTAT 30 Pouch is a hemostatic device for the control of severe, life-threatening bleeding from narrow entrance extremity wounds in the arms or legs in adults and adolescents.

XSTAT 30 Pouch is a temporary device for use up to six (6) hours until surgical care is acquired. It should only be used for patients at high risk for immediate life-threatening bleeding from, hemodynamically significant (Advanced Trauma Life Support class 3 or 4 hemorrhagic shock), non-compressible junctional wounds or narrow entrance extremity wounds, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT 30 Pouch is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.

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.

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510(k) SUMMARY
RevMedx, Inc. XSTAT 30 Pouch

Manufacturer Information:
RevMedx, Inc.
25999 SW Canyon Creek Road, Suite C
Wilsonville, OR 97070
Phone: 503-270-7828 (Mobile)
Facsimile: 503-218-2274
Contact Person: Amy K. Pointer, Director of RA/QA
Date Prepared: 03-02-2021 (Revised 08-26-2021)

Trade/Proprietary Name:
XSTAT 30 Pouch

Classification Name:
Non-Absorbable, Expandable, Hemostatic Sponge for Temporary Internal Use
Non-absorbable, Gauze/Sponge for external use

Product Classification & Code:
Class II
21 CFR 878.4452, PGZ
NAB

Predicate Devices:
XSTAT 30 Gen2 (K180051)

Reference Clearances: XSTAT 30 (DEN13006/K130218/K152624/K170334) and XSTAT 12 (K161020/K170334)

Intended Use / Indications for Use:

Intended Use:

XSTAT 30 Pouch is intended to be a hemostatic wound dressing.

Indications for Use:

XSTAT 30 Pouch is a hemostatic device for the control of severe, life-threatening bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents.

XSTAT 30 Pouch is a hemostatic device for the control of severe, life-threatening bleeding from narrow entrance extremity wounds in the arms or legs in adults and adolescents.

XSTAT 30 Pouch is a temporary device for use up to six (6) hours until surgical care is acquired. It should only be used for patients at high risk for immediate life-threatening bleeding from, hemodynamically significant (Advanced Trauma Life Support class 3 or 4 hemorrhagic shock), non-compressible junctional wounds or narrow entrance extremity wounds, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT 30 Pouch is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.

DEVICE DESCRIPTION:

XSTAT 30 Pouch:
The XSTAT 30 Pouch is comprised of the following components:

1. Minisponge Pouches (3 pouches per device)
2. Applicator/Plunger
3. Packaging and Labeling

The XSTAT 30 Pouch is a modified version of the company's legally marketed XSTAT 30 Gen2 device (K180051, "XSTAT 30 Gen2' or "predicate device"). The technological differences between the XSTAT 30 Pouch and the predicate device are:

- The enclosure of the minisponges in three (3) porous pouches to facilitate their removal from wounds;
- Changing the shape of the minisponges from round to hexagonal; and
- Including a radiopaque marker in each pouch in lieu of marking each individual minisponge.

The minisponge pouches are comprised of a tubular knit woven textile constructed with an ultra-high molecular weight polyethylene (UHMWPE) fiber. The pouch has a tensile strength of > 200 lbs and is resistant to tearing with surgical tools such as forceps and standard shears. The XSTAT 30 Pouch contains three (3) separate minisponge pouches within each applicator. A medical-grade radiopaque filament (barium sulfate-infused polypropylene) is attached on the interior of each of the three pouches.

The minisponges are comprised of a compressed cellulose sponge. When compressed, each minisponge has a height of approximately 5 mm and a surface diameter of 9 mm. Upon contact with blood, the minisponges absorb blood and, if unencumbered, are capable of expanding to a pre-compressed height of 40-50 mm within approximately 20 seconds. The sponge expands only in length (not width).

The applicator and plunger facilitates delivery of minisponge pouches to external bleeding wounds. Upon contact with blood, the minisponges absorb blood and expand to fill and pack the wound.

The applicator is a cylindrical body comprised of injection molded, medical grade polypropylene with an attached medical grade, phthalate-free PVC tip and an attached low density polyethylene (LDPE) end cap. The plunger is comprised of injection molded, 20% glass-filled polycarbonate and is used to deploy the minisponge pouches from the applicator.

One (1) applicator is filled with three (3) minisponge pouches and packaged with one (1) plunger in a vacuum-sealed nylon/poly package and terminally sterilized by gamma radiation to a sterility assurance level of 10^{-6}. The Instructions for Use (IFU) will be printed on or adhesively affixed to the package.

PERFORMANCE DATA

The company has conducted testing to characterize the performance of the XSTAT 30 Pouch. Protocols and results of the studies are summarized below.

Bench Testing

XSTAT 30 Minisponge Pouches

The following bench tests were performed for the subject device's Minisponge Pouches:

- Minisponge and Sponge Pouch Expansion Rate
- Minisponge Absorption Capacity
- Sponge Pouch Durability
- Sponge Pouch Expansion Force/Pressure in Gel Wound Model
- Sponge Pouch Radiopacity

XSTAT 30 Applicator

The subject device's applicator is identical to the applicator used in the XSTAT 30 Gen2 (predicate device). Thus, performance testing of the applicator has been demonstrated by the clearance of the XSTAT 30 Gen2 predicate device.

Deployment force testing (with and without fluid ingress, at both room temperature and low temperature conditions) was completed on the subject device's applicator to verify the safety and efficacy of the applicator design when used with the minisponge pouch(s).

XSTAT 30 Pouch Sterility Validation

The XSTAT 30 Pouch is sterilized by gamma radiation and are provided sterile for single patient use. Sterility Validation was performed per ISO 11137:2006 by the VDmax method. A VDmax of 25 kGy was used to demonstrate a sterility assurance level (SAL) of 10^{-6}, with a dose range of 25 – 40 kGy.

RevMedx performed tests on the XSTAT 30 Pouch to demonstrate that a sterility assurance level (SAL) of 10^{-6} is achieved with a minimum radiation dose of 25 kGy.

XSTAT 30 Pouch Shelf Life

The subject device's minisponges pouches were evaluated for shelf life per accelerated and real-time stability testing in accordance with ASTM F1980-16.

The subject device's applicator and barrier packaging is identical to the predicate device. Thus the shelf-life of these components have been demonstrated by premarket clearance of the predicate device (K180051).

Biocompatibility Testing

The subject device's minisponge pouches were evaluated for biocompatibility per ISO 10993 as a "Limited Duration (<24 Hours), implant device with tissue/bone contact".

The following biocompatibility tests were performed for the XSTAT 30 Sponge Pouch:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Materials-Mediated Pyrogenicity

The subject device's applicator is identical to the predicate device. Thus, the biocompatibility of the applicator has been demonstrated by the premarket clearance of the Predicate XSTAT 30 Gen2 device (K180051).

Animal Study

The company has conducted a GLP animal study to demonstrate the performance testing of the XSTAT 30 Pouch. The XSTAT 30 Pouch was compared to the predicate device, XSTAT 30, using a femoral animal injury model.

The GLP Femoral Animal Study demonstrates that the XSTAT 30 Pouch is as safe and effective as the predicate device.

Human Factors and Usability Testing

The subject device's applicator/plunger form factor and principles of operation are identical to the predicate device. Therefore, usability and human factors have been demonstrated by the premarket clearance of the Predicate XSTAT 30 Gen2 device (K180051).

In addition, the GLP Animal Study provided user observations and feedback regarding the ease and simplicity of minisponges pouch application and removal.

Substantial Equivalence

XSTAT 30 Pouch is as safe and effective as the predicate devices. XSTAT 30 Pouch has the same intended use, similar indications for use, same principles of operation and similar technological characteristics. The differences between the subject device and the predicate device do not present any new issues of safety or effectiveness because bench testing, biocompatibility testing and pre-clinical animal testing have shown that the XSTAT 30 Pouch is as safe and efficacious as the predicate device. Thus, the XSTAT 30 Pouch is substantially equivalent to the predicate device.

CONCLUSIONS

The XSTAT 30 Pouch is a modified version of the company's legally marketed XSTAT 30 Gen2 device (K180051, "XSTAT 30 Gen2' or "predicate device"). The XSTAT 30 Pouch is as safe and effective as the predicate device. The XSTAT 30 Pouch has the same intended use and similar indications for use. The XSTAT 30 Pouch has the same principles of operation and similar technological characteristics as the predicate device. The Substantial Equivalence Summary Table below details and compares the XSTAT 30 Pouch to the predicate XSTAT device.

Substantial Equivalence Summary Table – XSTAT 30 Pouch

Characteristic	New: XSTAT 30 Pouch	Predicate: XSTAT 30 Gen2 (K180051)
Intended Use	XSTAT 30 Pouch is intended to be a hemostatic wound dressing.	XSTAT 30 is intended to be a hemostatic wound dressing.
Indications for Use	XSTAT 30 Pouch is a hemostatic device for the control of severe, life-threatening bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents. XSTAT 30 Pouch is a hemostatic device for the control of severe, life-threatening bleeding from extremity wounds in the arms or legs in adults and adolescents. XSTAT 30 Pouch is a temporary device for use up to six (6) hours until surgical care is acquired. It should only be used for patients at high risk for immediate life-threatening bleeding from, hemodynamically significant (Advanced Trauma Life Support class 3 or 4 hemorrhagic shock), non-compressible junctional wounds or narrow entrance extremity wounds, and when definitive	XSTAT is a hemostatic device for the control of severe, life-threatening bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents. XSTAT is a hemostatic device for the control of severe, life-threatening bleeding from extremity wounds in the arms or legs in adults and adolescents. XSTAT is a temporary device for use up to four (4) hours until surgical care is acquired. It should only be used for patients at high risk for immediate life-threatening bleeding from, hemodynamically significant (Advanced Trauma Life Support class 3 or 4 hemorrhagic shock), non-compressible junctional wounds or narrow entrance extremity wounds, and when definitive

Characteristic	New: XSTAT 30 Pouch	Predicate: XSTAT 30 Gen2 (K180051)
	care at an emergency care facility cannot be achieved within minutes. XSTAT 30 Pouch is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space, the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.	care at an emergency care facility cannot be achieved within minutes. XSTAT is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space, the sacral space; tissues above the inguinal ligament; or tissues above the clavicle.
User Population	Civilian and battlefield patients Adults and Adolescents	Civilian and Battlefield patients Adults and Adolescents
Technological Characteristics	1. Minisponge Pouches (3/applicator) 2. Applicator 3. Packaging and Labeling	1. Minisponges 2. Applicator 3. Casualty Card 4. Packaging
Sponge Component	Three (3) porous, expanding pouches loaded into the applicator with hexagonal compressed cellulose minisponges. • ~36 minisponges/pouch • ~108 minisponges/applicator	Compressed cellulose minisponges loaded into the XSTAT 30 Gen2 Applicator • ~108 minisponges/applicator
Safety Features	Radiopaque marker attached to each pouch within the applicator	Radiopaque marker laminated to sponge with medical grade low-density polyethylene film
Dimensions (l x w x h)	1-Pack: 250mm (L) x 90mm (W) x 35mm (H)	1-Pack: 295mm x 180mm x 35mm
Weight	1-Pack: 0.07kg	1-Pack: 0.11kg
Biocompatibility	Cytotoxicity (ISO 10993-5); Sensitization (ISO 10993-10); Irritation (ISO 10993-10); Acute systemic toxicity (ISO 10993-11); and Materials-Mediated Pyrogenicity	Cytotoxicity (ISO 10993-5); Sensitization (ISO 10993-10); Irritation (ISO 10993-10); Acute systemic toxicity (ISO 10993-11); and Hemocompatibility (ISO 10993-4) Materials-Mediated Pyrogenicity
Sterilization	Gamma radiation sterilization	Gamma radiation sterilization