May 18, 2018

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

Re: K180051
Trade/Device Name: XSTAT 30, 1-Pack
Regulation Number: 21 CFR 878.4452
Regulation Name: Non-absorbable, Expandable, Hemostatic Sponge for Temporary Internal Use
Regulatory Class: Class II
Product Code: PGZ, NAB
Dated: February 27, 2018
Received: March 1, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VI. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement for each XSTAT Device is provided below.

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)*

K180051

Device Name

XSTAT 30

Indications for Use *(Describe)*

XSTAT 30 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 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 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 care at an emergency care facility cannot be achieved within minutes.

XSTAT 30 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
RevMedx, Inc. XSTAT 30 (K180051)

Manufacturer Information:
RevMedx, Inc.
25999 SW Canyon Creek Road, Suite C
Wilsonville, OR 97070
Phone: 503-218-2172
Facsimile: 503-218-2274
Contact Person: Amy K. Pointer, Director of RA/QA
Date Prepared: 12-15-2017

Trade/Proprietary Name:
XSTAT 30

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 and 21 CFR 828.4014, NAB

Predicate Devices:
XSTAT 30 and XSTAT 12 (K170334)

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

Intended Use / Indications for Use:

Intended Use:

XSTAT 30 is intended for the control of bleeding from wounds in the groin or axilla that are not amenable to tourniquet application or narrow entrance extremity wounds in the arms or legs in adults and adolescents.

Indications for Use:

XSTAT 30 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 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 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 care at an emergency care facility cannot be achieved within minutes.

XSTAT 30 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:

Description XSTAT 30:
The XSTAT 30 device consists of an applicator and plunger that facilitates delivery of minisponges to external bleeding wounds. Upon contact with blood, the minisponges absorb blood and, if unencumbered, can expand to a pre-compressed height of 40-50 mm within approximately 20 seconds.

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 minisponges from the applicator. One (1) applicator filled with ~ 108 minisponges and packaged with one (1) plunger in a vacuum-sealed nylon/poly pouch and terminally sterilized by gamma radiation to a sterility assurance level of 10^{-6}. The XSTAT 30 device consists of vacuum-sealed, gamma radiated, inner pouch, packaged inside a larger outer pouch as a one (1) pack configuration. Each outer pouch also contains one (1) casualty card and one (1) package insert. The Indications for Use, Instructions for Use (IFU) and UDI labels are affixed to the outer pouch, along with a UDI label on the inner pouch.

Performance Data
The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Applicator
Mechanical testing was completed on the XSTAT 30 applicator to verify the performance of the XSTAT 30 applicator design.

The following mechanical tests were performed and demonstrated the performance of the XSTAT 30 applicator and device:
- Deployment Force Testing
- Plunger Axial Force Testing
- Tip Tensile Strength Testing
- Fluid Immersion Testing

Minisponges
The XSTAT 30 minisponges are identical to the predicate devices. Thus, the testing defined in the Special Controls (as per 21 CFR 878.4452) related to minisponges (radiopacity, immunogenicity, absorption capacity, extent of swelling, expansion force/pressure and viral inactivation testing for animal-derived materials) has been demonstrated by the premarket clearance of the predicate devices (K170334). The testing provided in the cleared XSTAT 30 and XSTAT 12 notification (K170334) is incorporated herein by reference.

Biocompatibility Testing
The biocompatibility of the XSTAT 30 device was demonstrated per ISO 10993.
- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Acute System Toxicity (ISO 10993-11)
- Hemocompatibility (ISO 10993-4)
- Materials-Mediated Pyrogenicity

The XSTAT 30 minisponges are identical to the predicate devices. Thus, the biocompatibility testing per 21 CFR 878.4452 of the XSTAT 30 minisponges has been demonstrated per ISO 10993 by the premarket clearance of the Predicate XSTAT 30 and XSTAT 12 devices (K170334). The testing provided in the cleared XSTAT 30 and XSTAT 12 notification (K170334) is incorporated herein by reference.

Animal Study

The XSTAT 30 minisponges are identical to the predicate devices. Thus, the animal performance testing of the XSTAT 30 device (as per 21 CFR 878.4452) has been demonstrated by the premarket clearance of the predicate devices (K170334). The testing provided in the cleared XSTAT 30 and XSTAT 12 notification (K170334) is incorporated herein by reference.

Substantial Equivalence

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

Conclusions

The XSTAT 30 device is substantially equivalent to the predicate devices. The XSTAT 30 has the same intended use and indications for use, same principles of operation and similar technological characteristics. The Substantial Equivalence Summary tables below details and compares the XSTAT 30 to the predicate XSTAT devices.

Substantial Equivalence Summary Table – XSTAT 30

Characteristic	New: XSTAT 30	Predicate: XSTAT 30 and XSTAT 12 (K170334)
Intended Use	XSTAT 30 is intended for the control of bleeding from wounds in the groin or axilla that are not amenable to tourniquet application and narrow entrance extremity wounds in the arms or legs in adults and adolescents.	XSTAT is intended for the control of bleeding from wounds in the groin or axilla that are not amenable to tourniquet application and narrow entrance extremity wounds in the arms or legs in adults and adolescents.
Indications for Use	XSTAT 30 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 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 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 care at an emergency care facility cannot be achieved within minutes. XSTAT 30 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.	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 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. Minisponges 2. Applicator 3. Casualty Card 4. Packaging	1. Minisponges 2. Applicator 3. Casualty Card 4. Packaging
Dimensions (l x w x h)	1-Pack: 295mm x 180mm x 35mm	3-Pack: 254mm x 165mm x 38mm 1-Pack: 254mm x 165mm x 38mm
Weight	1-Pack: 0.11kg	3- Pack: 0.25kig 1-Pack: 0.1kg
Safety Features	Radiopaque marker laminated to sponge with medical grade low-density polyethylene film	Radiopaque marker laminated to sponge with medical grade low-density polyethylene film
Biocompatibility	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	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