DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 2016

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

Re: K161020
Trade/Device Name: XSTAT-12, 3-pack, XSTAT-12, 1-pack
Regulation Number: 21 CFR 878.4452
Regulation Name: Non-Absorbable, Exapandable, Hemostatic Sponge For Temporary Internal Use
Regulatory Class: Class II
Product Code: PGZ
Dated: June 23, 2016
Received: June 27, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K161020

Device Name

XSTAT-12

Indications for Use *(Describe)*

XSTAT-12 is a hemostatic device for the control of severe, life-threatening bleeding from wounds in the groin or axilla that are not amenable to tourniquet application in adults and adolescents.

XSTAT-12 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, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT-12 is NOT indicated for use in the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space, the sacral space above the inguinal ligament; or tissues above the clavicle.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) SUMMARY
RevMedx, Inc. XSTAT-12

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, RA/QA Manager
Date Prepared: 04/06/2016

Trade/Proprietary Name:
XSTAT-12

Classification Name:
Non-Absorbable, Expandable, Hemostatic Sponge for Temporary Internal Use

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

Predicate Devices:
XSTAT 30 (K152624)

Reference Device: XSTAT (DEN130016/K130218)

Intended Use / Indications for Use:
Intended Use:

The XSTAT-12 is intended for the control of bleeding from wounds in the groin or axilla that are not amenable to tourniquet application in adults and adolescents.

Indications for Use:

XSTAT-12 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-12 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, and when definitive care at an emergency care facility cannot be achieved within minutes.

XSTAT-12 is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space above the inguinal ligament; or tissues above the clavicle.

Device Description
The XSTAT-12 dressing is composed of a standard, regenerated cellulose medical sponge that is compressed and formed into a group of approximately 38 minisponges. Each minisponge has a height of 4-5 mm and a circular surface diameter of 9.8 mm. The minisponges absorb blood upon contact, and within approximately 20 seconds expand to their pre-compressed height of 40-50 mm. The minisponges expand only in length, not radially. Each minisponge absorbs approximately 3 mL of blood. Each minisponge contains a radiopaque marker for easy detection via X-ray. The XSTAT-12 dressing includes an applicator and plunger that facilitate delivery of the minisponges to external bleeding wounds. Individual applicators are filled with the STAT-12 minisponges and are packaged in a vacuum-sealed foil pouch with one (1) plunger, terminally sterilized by gamma radiation to a sterility assurance level of 10^{-6}. The inner pouches are then packaged inside a larger outer pouch, along with one (1) casualty card and one (1) package insert. The Instructions for Use (IFU) are affixed to the outer pouch.

For the treatment of severe, life-threatening bleeding from pelvis or shoulder wounds not amenable to tourniquet application, the XSTAT-12 sponges are applied to the wound using the applicator. Once applied to the wound, the XSTAT-12 sponges absorb blood and expand, thereby packing the wound. All minisponges must be removed from wounds before surgical repair and closure of the wounds. Following removal of the minisponges and definitive surgical repair of the wound, a radiograph is required prior to wound closure to confirm that every minisponge has been removed.

Performance Data
The following performance data were provided in support of the substantial equivalence determination and as required per 21 CFR 878.4452.

Mechanical Testing
Mechanical testing was completed on the XSTAT-12 applicator to verify the safety and efficacy of the XSTAT-12 applicator design when used in expected use scenarios, as well as in extreme temperature conditions.

The following mechanical tests were performed and demonstrated the safety and efficacy of the XSTAT-12 applicator and device:
- Deployment Force Testing
- Plunger Axial Force Testing
- Tip Tensile Strength Testing
- Fluid Immersion Testing
- Wound Volume Testing

The STAT-12 minisponges are identical to the predicate device. 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 device (K152624 and reference device DEN130016/K130218). The testing provided in the cleared XSTAT 30 notification (K152624) is incorporated herein by reference.

Biocompatibility Testing
The biocompatibility evaluation for the XSTAT-12 device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,” as recognized by FDA. The XSTAT-12 is an external communicating, limited duration (≤ 24 hour) contact device with potential for contact with tissue and/or bone, and indirect contact with circulating blood.

The battery of testing included the following tests:
- o Cytotoxicity
- o Sensitization
- o Irritation
- o System Toxicity
- o Hemocompatibility

The biocompatibility of the XSTAT-12 applicator was demonstrated per ISO 10993 for external communicating, limited duration (≤ 24 hour), blood-contacting devices.

The XSTAT-12 minisponges are identical to the predicate device. Thus the biocompatibility testing (as per 21 CFR 878.4452) of the XSTAT-12 minisponges has been demonstrated per ISO 10993 by the premarket clearance of the predicate device (K152624, reference device DEN130016/K130218). The testing provided in the cleared XSTAT 30 notification (K152624) is incorporated herein by reference.

Animal Study
The XSTAT-12 minisponges are identical to the predicate device. Thus the animal performance testing of the XSTAT-12 (as per 21 CFR 878.4452) has been demonstrated by the premarket clearance of the predicate device (K152624, reference device DEN130016/K130218). The testing provided in the cleared XSTAT 30 notification (K152624) is incorporated herein by reference.

Substantial Equivalence

The XSTAT-12 is as safe and effective as the XSTAT 30. The XSTAT-12 and XSTAT 30 have the same intended use and indications for use, similar principles of operation and similar technological characteristics. There are no differences to the minisponges used in XSTAT-12 as compared to XSTAT 30, with the quantity of sponges per applicator being the only difference. The differences between the XSTAT-12 and XSTAT 30 predicate device do not present any new issues of safety or effectiveness because the use of a smaller applicator design with fewer minisponges raises the same questions of safety and effectiveness as the predicate device. The minor differences in the applicator are based upon a similar, syringe-like design to aid in the delivery of the XSTAT minisponges to the wound, but with a smaller diameter to allow XSTAT minisponges to be used in smaller diameter wounds. Thus, the XSTAT-12 is substantially equivalent to the XSTAT 30.

Conclusions

The XSTAT-12 is as safe and effective as the predicate XSTAT 30 device. The intended use and indications for use are the same for both XSTAT-12 and XSTAT 30, with similar principles of operation and similar technological characteristics. The Substantial Equivalence Summary table below details and compares the XSTAT-12 to the XSTAT 30.

Substantial Equivalence Summary Table

Characteristic	XSTAT-12 - New	XSTAT 30 – Predicate (K152624)
Intended Use	XSTAT-12 is intended for the control of bleeding from wounds in the groin or axilla that are not amenable to tourniquet application in adults and adolescents.	XSTAT 30 is intended for the control of bleeding from wounds in the groin or axilla that are not amenable to tourniquet application in adults and adolescents.
Indications for Use	XSTAT-12 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-12 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, and when definitive care at an emergency care facility cannot be achieved within minutes. XSTAT-12 is NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space, the sacral space above the inguinal ligament; or tissues above the clavicle.	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 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, and when definitive care at an emergency care facility cannot be achieved within minutes. XSTAT 30 NOT indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space, the sacral space above the inguinal ligament; or tissues above the clavicle.
User Population	Civilian and battlefield patients	Civilian and Battlefield patients
Technological Characteristics	1. Minisponges 2. Applicator 3. Insert/Casualty Card 4. Packaging	1. Minisponges 2. Applicator 3. Insert/Casualty Card 4. Packaging
Dimensions (l x w x h)	3-Pack: 292mm x 171mm x 19mm 1-Pack: 292mm x 171mm x 19mm	3-Pack: 254mm x 165mm x 38mm 1-Pack: 254mm x 165mm x 38mm
Weight	3- Pack: 0.123kg 1-Pack: 0.055kg	3- Pack: 0.25kig 1-Pack: 0.1kg
Safety Features	Radiopaque marker	Radiopaque marker
Biocompatibility	Cytotoxicity (ISO 10993-5); Sensitization (ISO 10993-10); Irritation (ISO 10993-10); Acute systemic toxicity (ISO 10993-11); and Hemocompatibility (ISO 10993-4)	Cytotoxicity (ISO 10993-5); Sensitization (ISO 10993-10); Irritation (ISO 10993-10); Acute systemic toxicity (ISO 10993-11); and Hemocompatibility (ISO 10993-4)
Sterilization	Gamma radiation sterilization	Gamma radiation sterilization