



Food and Drug Administration
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December 7, 2015

RevMedx Incorporated
John J. Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, DC 20004

Re: K152624

Trade/Device Name: XSTAT 30

Regulation Number: 21 CFR 878.4452

Regulation Name: Nonabsorbable expandable hemostatic sponge for temporary internal use

Regulatory Class: Class II

Product Code: PGZ

Dated: September 14, 2015

Received: September 14, 2015

Dear Dr. Smith:

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" (21CFR 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,

Binita S. Ashar -S

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

Indications for Use

510(k) Number (if known)

Device Name

XSTAT 30

Indications for Use (Describe)

XSTAT 30 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 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, 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 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)

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)

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510(k) SUMMARY
RevMedx, Inc. XSTAT 30

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: September 14, 2015

Trade/Proprietary Name:

XSTAT 30

Classification Name:

Non-Absorbable, Expandable, Hemostatic Sponge for Temporary Internal Use

Product Classification & Code:

21 CFR 878.4452; PGZ

Predicate Devices:

XSTAT (DEN130016; K130218)

Intended Use / Indications for Use:

Intended Use:

The 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 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 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.

Technological Characteristics

The XSTAT 30 dressing is composed of a standard, regenerated cellulose medical sponge that is compressed and formed into a group of approximately 92 mini-sponges. Each mini-sponge has a height of 4-5 mm and a circular surface diameter of 9.8 mm. The compressed regenerated cellulose sponge is coated with chitosan. Upon contact with blood, the mini-sponges absorb blood and, if unencumbered, are capable of expanding to a pre-compressed height of 40-50 mm within approximately 20 seconds. A radiopaque marker is embedded into a circular surface of the mini-sponges to render each sponge detectable via X-ray. The XSTAT 30 dressing includes an applicator that facilitates delivery of the mini-sponges to external bleeding wounds. Three applicators filled with the XSTAT 30 dressing (i.e., mini-sponges) are packaged in a sealed foil pouch and terminally sterilized by gamma radiation to a sterility assurance level of 10^{-6} .

For the treatment of severe bleeding from pelvis or shoulder wounds not amenable to tourniquet application, the XSTAT 30 sponges are applied to the wound using the applicator. Once applied to the wound, the XSTAT 30 sponges absorb blood and expand, thereby packing the wound. All mini-sponges must be removed from wounds before surgical repair and closure of the wounds. Following removal of the mini-sponges and definitive surgical repair of the wound, a radiograph is required prior to wound closure to confirm that every mini-sponge has been removed.

Performance Data

The technological characteristics for XSTAT 30 are identical to the predicate device. Thus, the performance testing of the XSTAT 30 has been demonstrated by the clearance of the XSTAT predicate device. The testing provided in the cleared XSTAT notification (K130218) is incorporated herein by reference.

Substantial Equivalence

XSTAT 30 and XSTAT have the same intended use, same technological characteristics, same principles of operation and similar indications. The difference between the devices is a change to the indications for use. The X-Stat devices have a specific indication for use to control hemorrhage from non-compressible junctional wounds. This type of wound is equally life threatening when sustained in either a combat environment or a civilian environment, where there may be a delay to expeditious surgical intervention. When available at the point of injury, X Stat 30 can help minimize blood loss and provide a bridge to surgery. Therefore, XSTAT 30 is substantially equivalent to XSTAT.

Conclusions

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

Substantial Equivalence Summary Table

	XSTAT 30	XSTAT (K130218)
Intended Use	Same	Same
Indications for Use	<p>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.</p> <p>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.</p> <p>XSTAT 30 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.</p>	<p>XSTAT is a hemostatic device for the control of bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents.</p> <p>XSTAT is a temporary device for use up to four (4) hours until surgical care is acquired. XSTAT is intended for use in the battlefield.</p> <p>XSTAT 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.</p>
User Population	Civilian and battlefield patients	Battlefield patients
Technological Characteristics	<ol style="list-style-type: none"> 1. Mini-sponges 2. Applicator 3. Casualty Card 4. Packaging 	<ol style="list-style-type: none"> 1. Mini-sponges 2. Applicator 3. Casualty Card 4. Packaging
Dimensions (l x w x h)	3-Pack: 254mm x 165mm x 38mm 1-Pack: 254mm x 165mm x 38mm	3-Pack: 254mm x 165mm x 38mm 1-Pack: 254mm x 165mm x 38mm
Weight	3- Pack: 0.25kg 1-Pack: 0.1kg	3- Pack: 0.25kg 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