August 11, 2017

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

Re: K170334
Trade/Device Name: XSTAT 30, 3-Pack; XSTAT 30, 1-Pack; XSTAT 12, 3 Pack; XSTAT 12, 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
Dated: January 31, 2017
Received: February 2, 2017

Dear Ms. Pointer:

This letter corrects our substantially equivalent letter of May 1, 2017.

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,

Peter L. Hudson -S
2017.08.11 11:00:20 -04'00'

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
Indications for Use

510(k) Number (if known)
K170334

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 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 from, immediate life-threatening 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.

“DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.”

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
Indications for Use

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 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 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 from immediate life-threatening 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 12 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)
- [X] 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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FORM FDA 3981 (8/14)
510(k) SUMMARY (Revised per K170334 Amendment)
RevMedx, Inc. XSTAT 30 and 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, Director of RA/QA
Date Prepared: 07/03/2017

Trade/Proprietary Name:
XSTAT 30 (Device #1)
XSTAT 12 (Device #2)

Classification Name:
Non-Absorbable, Expandable, Hemostatic Sponge for Temporary Internal Use (1)
Non-Absorbable Gauze/Sponge for External use (2)

Product Classification & Code:
21 CFR 878.4452; PGZ, Class II (1)
21 CFR 878.4014, NAB, Class I (2)
NOTE: Product Classification is Class II

Predicate Devices:
XSTAT 30 (K152624)
XSTAT 12 (K161020)

Reference Device: XSTAT (DEN13006/K130218)

Intended Use / Indications for Use:

Intended Use - Device #1:
The 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.

Intended Use - Device #2:
The XSTAT 12 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 – Device #1:
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 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

**Indications for Use – Device #2:**

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 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 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 or narrow entrance extremity 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; tissues above the inguinal ligament; or tissues above the clavicle.

**Device Description:**

**Description - Device #1 (XSTAT 30):**

The XSTAT 30 device consists of an applicator that facilitates delivery of minisponges to external bleeding wounds. The applicator with a telescoping handle is filled with ~ 92 minisponges and packaged in a vacuum-sealed foil pouch and terminally sterilized by gamma radiation to a sterility assurance level of $10^{-6}$. The XSTAT 30 3-pack consists of three (3) applicators in an individually sealed foil pouch and terminally sterilized by gamma radiation. The Instructions for Use ("IFU") are printed on the outside of the sterile packaging. One (1) product insert summarizing preclinical testing and one (1) casualty card is included with the packaging. The XSTAT 30 1-pack consists of one (1) applicator in an individually sealed foil pouch and terminally sterilized by gamma irradiation. The Instructions for Use (IFU) are printed on the outside of the sterile packaging. One (1) product insert summarizing preclinical testing and one (1) casualty card is included with the packaging.

**Description - Device #2 (XSTAT 12):**

The XSTAT 12 device consists of an applicator and plunger that facilitate delivery of minisponges to external bleeding wounds. Individual applicators are filled with minisponges and are packaged in a vacuum-sealed foil pouch with one (1) plunger, and terminally sterilized by gamma radiation to a sterility assurance level of $10^{-6}$. The XSTAT 12 device consists of vacuum-sealed, gamma radiated, inner pouches which are packaged inside a larger outer pouch as a three (3) pack or one (1) pack configuration. Each outer pouch also contains one (1) casualty card and one (1) package insert. The Instructions for Use (IFU) are affixed to the outer pouch.

**Description – Minisponges (XSTAT Devices):**

The XSTAT devices comprise standard, regenerated cellulose medical sponge that is compressed and formed into 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. Each minisponge contains a radiopaque marker for easy detection via X-ray.

For the treatment of severe, life-threatening bleeding from pelvis or shoulder wounds not amenable to tourniquet application or narrow entrance extremity wounds, the XSTAT minisponges are applied to the wound using the applicator. Once applied to the wound, the XSTAT minisponges 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.

Bench Testing

Applicator

As referenced in K170334, the XSTAT 30 and XSTAT 12 applicators are identical to the predicate devices. Thus the mechanical testing of the XSTAT 30 and XSTAT 12 applicators was demonstrated by the premarket clearance of the Predicate XSTAT 30 device (K152624) and the Predicate XSTAT 12 device (K161020).

Minisponges

As provided in K170334, the following bench tests were performed to verify the properties and performance of the XSTAT minisponges:

- Radiopacity and Radiopaque Marker Durability
- Immunogenicity
- Absorption Capacity
- Extent of Swelling
- Expansion Force/Pressure

Biocompatibility Testing

As provided in K170334, the biocompatibility of the XSTAT minisponges was demonstrated per ISO 10993. As referenced in K170334, the XSTAT 30 and XSTAT 12 applicators are identical to the predicate devices. Thus the biocompatibility testing per 21 CFR 878.4452 of the XSTAT 30 applicator has been demonstrated per ISO 10993 by the premarket clearance of the Predicate XSTAT 30 device (K152624), and the Predicate XSTAT 12 device (K161020).

Animal Study

As provided in K170334, the XSTAT 30 was tested with GLP animal studies as defined in the special controls for Product Classification (PGZ, as per 21 CFR 878.4452). XSTAT 12 uses the same minisponges as the XSTAT 30, so the principle of operation for the minisponges are identical. Therefore, the GLP animal testing of the minisponges using the XSTAT 30 applicator are fully applicable to the XSTAT 12 device. The animal studies demonstrate that the XSTAT 30 and XSTAT 12 minisponges are as safe and effective as the minisponges used in the predicate devices.
Substantial Equivalence

As cleared per K170334, XSTAT 30 and XSTAT 12 are as safe and effective as the predicate devices. XSTAT 30 and XSTAT 12 have the same intended use and indications for use, same principles of operation and similar technological characteristics of the predicate Class II devices. The differences between the subject devices and their respective predicates 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 and XSTAT 12 are as safe and efficacious as the predicate devices.

The co-labelled indications for use (Class II, PGZ, along with Class I, NAB) do not present any new issues of safety or effectiveness because bench testing, biocompatibility testing and pre-clinical animal studies have shown that XSTAT 30 and XSTAT 12 are safe and effective for the Class I indication for use. Thus, the XSTAT 30 and XSTAT 12 are substantially equivalent to the predicate devices.

Conclusions

The XSTAT 30 and XSTAT 12 are as safe and effective as the predicate devices. The XSTAT 30 and XSTAT 12 have the same intended use and indications for use, same principles of operation and similar technological characteristics of the predicate Class II devices. The Substantial Equivalence Summary tables below details and compares the XSTAT 30 and XSTAT 12 to the predicate XSTAT devices.

The co-labelled indications for use (Class II, PGZ, along with Class I, NAB) do not present any new issues of safety or effectiveness because bench testing, biocompatibility testing and pre-clinical animal studies have shown that XSTAT 30 and XSTAT 12 are safe and effective for the Class I indication for use. Thus, the XSTAT 30 and XSTAT 12 are substantially equivalent to the predicate devices.