



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

RevMedx, Inc
c/o John Smith, M.D., J.D.
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20004

Re: K130218
XSTAT
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21CFR 878.4452
Regulation Name: Non-absorbable, expandable, hemostatic sponge for temporary internal use
Regulatory Classification: Class II
Product Code: PGZ
Dated: January 28, 2013
Received: January 30, 2013

Dear Dr. Smith:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of XSTAT, a prescription device under 21 CFR Part 801.109 that is indicated as 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. 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. 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. FDA concludes that this device should be classified into class II. This order, therefore, classifies the XSTAT, and substantially equivalent devices of this generic type, into class II under the generic name, Non-absorbable, expandable, hemostatic sponge for temporary internal use.

FDA identifies this generic type of device as:

Non-absorbable, expandable, hemostatic sponge for temporary internal use. A non-absorbable, expandable, hemostatic sponge for temporary internal use is a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile, non-absorbable, radiopaque, compressed sponges and may include an applicator to facilitate delivery into a wound.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On January 30, 2013, FDA received your *de novo* requesting classification of XSTAT into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify XSTAT into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that XSTAT indicated as 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. 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. 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 can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Method
Failure to Stop Bleeding or Recurrence of Bleeding	Non-Clinical Performance Data <i>In Vivo</i> Performance Data Stability Assessment Labeling
Obstruction of Vital Organs	Human Factors Testing Labeling
Embolization	<i>In Vivo</i> Performance Data

Collateral Tissue Damage (e.g., paralysis, nerve damage, tissue necrosis)	<i>In Vivo</i> Performance Data Labeling
Adverse Tissue and Allergic Reactions	Material Characterization Biocompatibility <i>In Vivo</i> Performance Data Labeling
Infection (e.g., cellulitis, Toxic Shock Syndrome, sepsis)	Sterility Testing Stability Assessment
Reoperation Due to Material Retained in Body	Non-Clinical Performance Data <i>In Vivo</i> Performance Data Human Factors Testing Labeling
Sponge Deployment Failure	Non-Clinical Performance Data <i>In Vivo</i> Performance Data Stability Assessment Human Factors Testing Labeling
Improper Application Technique or Use Error	Human Factors Testing Labeling

In combination with the general controls of the FD&C Act, the Non-absorbable, expandable, hemostatic sponge for temporary internal use is subject to the following special controls:

1. Performance data must demonstrate the biocompatibility of patient-contacting components.
2. Performance data must demonstrate the sterility of patient-contacting components including endotoxin and pyrogenicity assessments.

3. Performance data must support device stability by demonstrating continued sterility of the patient-contacting components of the device, package integrity, and device functionality over the requested shelf life.
4. Assessment of material characteristics must be sufficient to support safety under anticipated conditions of use. Assessments must include the following:
 - A. Material specifications
 - B. Immunogenicity
 - C. Viral inactivation for animal-derived materials
5. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - A. Absorption capacity
 - B. Extent of swelling
 - C. Mechanical properties
 - D. Expansion force/pressure
 - E. Radiopacity
 - F. Deployment/applicator functionality
6. *In vivo* performance data must demonstrate safe and effective use by verifying that the device performs as intended under anticipated conditions of use. Appropriate analysis/testing must demonstrate that the product: controls bleeding, does not promote adverse local or systemic effects, and can be completely removed from the wound. The following performance characteristics must be tested:
 - A. Deployment
 - B. Control of bleeding
 - C. Radiopacity
 - D. Retrieval
 - E. Assessment of local and systemic effects
7. Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by emergency responders deploying the device as well as surgeons retrieving the device from wounds.
8. Labeling must include:
 - A. Specific instructions for deployment by emergency responders and retrieval by surgeons
 - B. Warnings, cautions, and limitations needed for safe use of the device
 - C. Information on how the device operates and the typical course of treatment
 - D. A detailed summary of the *in vivo* and human factors testing pertinent to use of the device
 - E. Appropriate imaging information to ensure complete retrieval of device
 - F. An expiration date/shelf life

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification

requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Non-absorbable, expandable, hemostatic sponge for temporary internal use they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request 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.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Kelley Burrige, Ph.D., at 301.796.6970.

Sincerely yours,

Jonette R. Foy -S

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