November 12, 2025

RevMedx, Inc.
Amy Pointer
Director of RA/QA
25749 S W Canyon Creek Rd.
Suite 300
Wilsonville, Oregon 97070

Re: K253290
Trade/Device Name: Xstat P15
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 25, 2025
Received: September 29, 2025

Dear Amy 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253290

Device Name
XSTAT P15

Indications for Use *(Describe)*

XSTAT P15 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 P15 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 P15 is a temporary device for use up to six (6) 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 P15 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.

510(k) SUMMARY
K253290

Manufacturer Information:
RevMedx, Inc.
25749 SW Canyon Creek Road, Suite 300
Wilsonville, OR 97070
Phone: 503-270-7828 (Mobile)
Contact Person: Amy K. Pointer, Director of RA/QA
Date Prepared: 09-25-2025

Trade/Proprietary Name:
XSTAT P15

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

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

Predicate Devices:
XSTAT P30 (K210676)

Intended Use / Indications for Use:

Intended Use:

XSTAT P15 is intended to be a hemostatic wound dressing.

Indications for Use:
XSTAT P15 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 P15 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 P15 is a temporary device for use up to six (6) 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 P15 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.

Contraindications:
XSTAT P15 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:

The XSTAT P15 is comprised of the following components:

1. Minisponge Pouch (1 pouch per device)
2. Applicator/Plunger
3. Packaging and Labeling

The syringe-style applicator is used to deliver the minisponge pouch into bleeding wounds. Upon contact with blood, the minisponges rapidly expand to fill and pack the wound cavity.

The applicator and plunger are injection-molded from medical-grade polypropylene and packaged in a vacuum-sealed nylon/poly pouch. Each unit is terminally sterilized by gamma radiation (SAL 10^{-6}). The Instructions for Use (IFU) is printed on or affixed to the packaging.

Performance Data:

The company has conducted testing to characterize the performance of the XSTAT P15.

Bench Testing - Applicator and Plunger

Mechanical bench testing was conducted to evaluate the functional performance of the XSTAT P15 applicator and plunger. The following tests were performed:

- Plunger Axial Load Verification
- Deployment Force Testing
- Applicator Fluid Immersion Testing
- Tip Tensile Strength Testing

Bench Testing – Minisponges

The minisponges used in the XSTAT P15 are identical in composition, quantity, and performance to those in the predicate device. Predicate testing included:

- Sponge Expansion Rate
- Absorption Capacity
- Expansion Force / Gel Wound Model Testing

The performance testing for the minisponge component is supported by the previously cleared XSTAT P30 (K210676) and is incorporated herein by reference.

Bench Testing - Pouch

The sponge pouch materials and construction are identical to the predicate device, with the only change being a 2 cm increase in length. Testing conducted on the predicate supports the following:

- Pouch Durability
- Pouch Radiopacity

No new risks were introduced by the dimensional modification. The performance testing for the minisponge pouch component is supported by the previously cleared XSTAT P30 (K210676) and is incorporated herein by reference.

Sterility Validation:

The XSTAT P15 is terminally sterilized by gamma radiation (SAL 10^{-6}). All sterile components are materially identical to those cleared in K210676. The validation of sterility is supported by the previously cleared XSTAT P30 submission and is incorporated herein by reference.

Shelf Life:

A five-year shelf life is supported by real-time and accelerated aging studies. All device materials are identical to those of the predicate device, and the minor dimensional changes do not impact shelf life. The shelf life validation is supported by the previously cleared XSTAT P30 submission (K210676) and is incorporated herein by reference.

Biocompatibility Testing:

A risk-based biological evaluation was conducted in accordance with ISO 10993-1 and FDA's 2023 guidance. All patient-contacting materials are unchanged from the predicate. No new risks were identified. The biocompatibility is supported by the previously cleared XSTAT P30 submission (K210676) and is incorporated herein by reference.

Animal Study:

Animal performance testing submitted in support of the XSTAT P30 clearance remains applicable to the XSTAT P15. No new materials or functional changes were introduced that would necessitate new animal testing. The animal data is supported by the previously cleared XSTAT P30 submission (K210676) and are incorporated herein by reference.

Human Factors and Usability Testing:

The user steps, operating environment, and IFU for XSTAT P15 are identical to those of the predicate device. No new human factors risks were identified. Usability is supported by the previously cleared XSTAT P30 submission (K210676) and are incorporated by reference.

Substantial Equivalence:

XSTAT P15 has the same intended use, indications for use, and principle of operation as the predicate device. The technological differences are minor and do not raise new questions of safety or effectiveness. Bench testing, risk analyses, and prior performance data support the conclusion that XSTAT P15 is as safe and effective as the predicate. Therefore, the XSTAT P15 is substantially equivalent to the XSTAT P30 (K210676).

Conclusions:

The XSTAT P15 is as safe and effective as the predicate device. The XSTAT P15 has the same intended use, indications for use and principes of operations, and similar technological characteristics. The Substantial Equivalence Summary Table below details and compares the XSTAT P15 to the predicate XSTAT P30 device.

Substantial Equivalence Summary Table – XSTAT P15

Characteristic	New: XSTAT P15	Predicate: XSTAT P30 (K210676)
Intended Use	XSTAT P15 is intended to be a hemostatic wound dressing.	Same
Indications for Use	XSTAT P15 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 P15 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 six (6) 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. facility cannot be achieved within minutes. XSTAT P15 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.	Same
Contraindications	XSTAT P15 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.	Same
User Population	Civilian and battlefield patients Adults and Adolescents	Same
Principles of Operation	Syringe-style applicator delivers minisponge pouch into wound; sponges expand upon contact with blood to tamponade bleeding.	Same
Technological Characteristics	• One (1) minisponge pouch per applicator (~36 minisponges) • Smaller-diameter applicator (~16 mm)	• Three (3) minisponge pouches per applicator (~108 minisponges) • Larger applicator (~28 mm)
Package Dimensions (l x w x h)	1-Pack: 216mm (L) x 90mm (W) x 24mm (H)	1-Pack: 250mm (L) x 90mm (W) x 35mm (H)
Weight	~0.03 kg	~0.07 kg
Safety Features	Radiopaque marker embedded in each pouch	Same
Biocompatibility	Evaluated per ISO 10993-1 (cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity)	Same
Sterilization	Gamma radiation (SAL 10^{-6})	Same