



April 30, 2026

LifeScience PLUS, Inc.
Audrey Vitale
QA/QMS Director
2520A Wyandotte St.
Mountain View, California 94043

Re: K253017
Trade/Device Name: BloodSTOP iX Trauma Matrix
Regulatory Class: Unclassified
Product Code: QSY
Dated: March 18, 2026
Received: March 19, 2026

Dear Audrey Vitale:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,


Yu-chieh Chiu -S

Yu-Chieh Chiu, 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

Indications for Use

510(k) Number (if known)
K253017

Device Name

BloodSTOP iX Trauma Matrix

Indications for Use (Describe)

BloodSTOP iX Trauma Matrix is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for external temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

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.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

LifeScience PLUS, Inc.
2520A Wyandotte St.,
Mountain View, CA 94043
Tel: 1-650.565.8172
Fax: 1-650.336.1130
Contact Person: Audrey Vitale
Date Prepared: April 28, 2026

II. DEVICE

| | |
|------------------------------|---|
| Device Trade Name: | BloodSTOP iX Trauma Matrix |
| Classification Name: | Hemostatic Wound Dressing Without Thrombin Or Other Biologics |
| Regulation: | Not Applicable |
| Regulatory Class: | Unclassified |
| Device Panel: | General and Plastic Surgery |
| Product Classification Code: | QSY |

III. PREDICATE AND REFERENCE DEVICE

| | |
|-------------------------|-------------------------------|
| Predicate Manufacturer: | Z-Medica, LLC |
| Predicate Trade Name: | Quikclot® Hemostatic Dressing |
| Predicate 510(k): | K123387 |

| | |
|-------------------------|----------------------------|
| Reference Manufacturer: | Core Scientific, Ltd. |
| Reference Trade Name: | WoundClot Hemostatic Gauze |
| Reference 510(k): | K140573 |

IV. DEVICE DESCRIPTION

BloodSTOP iX Trauma Matrix is a sterile wound dressing composed of etherified, oxidized, regenerated cellulose (chemical name, sodium carboxymethyl cellulose). When contacting blood and exudates, it absorbs blood, transforms into a gel, adheres to the wound. It contains no human nor animal biological substances, nor medicinal substances. It is provided in soft fabric-like dressing format, and is applied topically with pressure, in the same way as other hemostatic dressings. It is provided in various sizes, and is packaged in a tear-open sterile barrier pouch, sterilized with gamma radiation to a sterility assurance level (SAL) of 10^{-6} .

V. INDICATIONS FOR USE

BloodSTOP iX Trauma Matrix is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for external temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

| Parameter | Subject Device, K253017 BloodSTOP® iX Trauma Matrix (TM) | Predicate Device, K123387 Quikclot® Hemostatic Dressing (QC) (also marketed as QuikClot Combat Gauze) | Reference Device, K140573 WoundClot Hemostatic Gauze (WC) | Comment |
|--|---|--|--|--|
| Intended/Indications for Use | Intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for external temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries. | Intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries. | Intended to be used as a topical dressing for local management of bleeding wounds, such as cuts, lacerations and abrasions, and for use as a temporary treatment of severely bleeding wounds, such as surgical wounds (operative, postoperative, donor sites, dermatological) and traumatic injuries | Same |
| Rx/OTC | Rx | Rx | Rx | Same |
| Anatomical Site and Duration of Exposure | Breached or compromised surface, limited duration (≤ 24 hours) | Breached or compromised surface, limited duration (≤ 24 hours) | Breached or compromised surface, limited duration (≤ 24 hours) | Same |
| Single Use | Yes | Yes | Yes | Same |
| Materials | Etherified oxidized regenerated cellulose (Chemical name: sodium carboxymethyl cellulose) | Kaolin impregnated dressing | Regenerated cellulose, chemically treated to become water-soluble | The predicate hemostatic agent is kaolin, impregnated in the dressing. In Subject and Reference devices, the hemostatic agent is the dressing material itself. |
| Design | Soft, off-white, intuitive, easy-to-use, single-use, sterile dressing format that readily conforms to wound. Various sizes including 2"x14" and 3"x24", both z-folded; and 12"x12" folded pad. | Soft, off-white, intuitive, easy-to-use, single-use, sterile dressing format that readily conforms to wound. Various sizes including 4" x 4-yard strip, z-folded; 3" x 4-yard strip, z-folded; 12" x 12" pad. | Soft, off-white, intuitive, easy-to-use, single-use, sterile dressing format that readily conforms to wound. Various sizes including 8"x10" and 3"x 40" | Same |
| Application | Applied to wound with pressure | Applied to wound with pressure | Applied to wound with pressure | Same |
| Removal | Mechanically, with hydration to avoid disturbing the clot | Mechanically, with hydration to avoid disturbing the clot | Mechanically, with hydration to avoid disturbing the clot | Same |
| Drug or Biologic Component | No | No | No | Same |

| | | | | |
|---------------------|---|--|--|--|
| Biocompatibility | Biocompatible according to updated 2023.09.08 FDA Guidance, Use of International Standard ISO 10993-1 | Acceptable results to tests required according to FDA FDA 510(k) Memorandum G95-1, ISO 10993-1 | Acceptable results to tests required according to FDA FDA 510(k) Memorandum G95-1, ISO 10993-1 | Subject device is biocompatible according to updated 2023.09.08 FDA guidance on the use of ISO 10993-1. Predicate and reference devices complied with FDA Guidance on ISO 10993-1 at the time of submission. |
| Packaging | Sterile barrier, 3-layer tear open poly pouch, single use only | Sterile barrier, tear open metalized poly "Foil" pouch, single use only | Sterile barrier, tear open poly pouch, single use only | All are sterile barrier single use, tear open pouches |
| Sterilization | Radiation Sterilization to SAL of 10 ⁻⁶ | Radiation Sterilization to SAL of 10 ⁻⁶ | Radiation Sterilization | Same |
| Performance Testing | Performs as well as QuikClot Combat Gauze in model of Extremity Arterial (femoral artery) Hemorrhage in Swine | History established using model of Extremity Arterial (femoral artery) Hemorrhage in Swine | A severe bleeding swine model of femoral arteriotomy was conducted against its predicate device, BeneCel (K080532) | Safety and efficacy of the subject device is demonstrated compared to the predicate using a widely recognized 6mm femoral artery injury model in swine. |

BloodSTOP iX Trauma Matrix is substantially equivalent to the legally marketed predicate Quikclot, K123387.

- The devices have the identical intended use, and substantially similar design, composition, and mechanism of action.
- Both are intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. They may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.
- Both are intuitive, simple to use, single-use, sterile, hemostatic dressings. Both absorb blood.
- While the hemostatic agent for the predicate, kaolin mineral powder, is impregnated into a gauze dressing; the BloodSTOP iX Trauma Matrix material, etherified oxidized regenerated cellulose, is itself the hemostatic agent.
- [The reference device, WoundClot (K140573) hemostatic dressing, is also made from regenerated cellulose, and is itself the hemostatic agent.]

Although the hemostatic components of BloodSTOP iX Trauma Matrix and the predicate are different, their mechanism of action and outcome is substantially similar. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

STERILIZATION & SHELF-LIFE TESTING

- BloodSTOP iX Hemostat Trauma Matrix is terminally sterilized using gamma radiation to a Sterility Assurance Level (SAL) of 10⁻⁶.
- Shelf-life of BloodSTOP iX Hemostat Trauma Matrix is 5 years.

BIOCOMPATIBILITY TESTING

Biocompatibility tests have been performed per the requirements of 2023.09.08 FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* for surface devices used on breached or compromised surface with limited contact duration (≤ 24 hours). The subject device complies as follows in the below table:

| Test | Test (Standard) | Conclusion |
|-------------------------|--|-----------------|
| Cytotoxicity | ISO MEM Elution Method (USP, ISO 10993-5:2009) | Non-cytotoxic |
| Sensitization | ISO Guinea Pig Maximization Sensitization (ISO 10993-10:2021) | Non-sensitizing |
| Irritation | ISO Intracutaneous Reactivity (ISO 10993-10:1996) | Non-irritating |
| Acute Systemic Toxicity | ISO Acute Systemic Toxicity (ISO 10993-11:2017) | Non-toxic |
| Pyrogenicity | ISO Materials Mediated Rabbit Pyrogen (ISO 10993-11:2017; USP Pyrogen Test) | Non-pyrogenic |

PRE-CLINICAL ANIMAL TESTING

The hemostatic efficacy and safety of BloodSTOP iX Hemostat Trauma Matrix and the predicate device were tested in a lethal porcine model of femoral arterial hemorrhage. Primary endpoints included hemostasis success rate, blood loss volume, fluid resuscitation requirements, and hemodynamic stability. Secondary endpoints included clinical pathology and histopathology. Results demonstrated substantially equivalent performance of BloodSTOP iX Trauma Matrix as compared to the predicate.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, and comparison to predicate device, with performance data including bench and pre-clinical animal testing, BloodSTOP iX Trauma Matrix has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.