U.S. FOOD & DRUG ADMINISTRATION

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

April 21, 2023

Re: K160130
Trade/Device Name: BloodSTOP iX Battle Matrix
Regulatory Class: Unclassified
Product Code: QSY

Dear Audrey Vitale:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 29, 2016. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 29, 2016

LifeScience Plus, Inc.
Ms. Audrey Vitale
Director of QA/QMS
2520A Wyandotte St.
Mountain View, CA 94043

Re: K160130
Trade/Device Name: BloodSTOP iX Battle Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 24, 2016
Received: May 26, 2016

Dear Ms. 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 (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,

David Krause -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160130

Device Name
BloodSTOP iX Battle Matrix

Indications for Use *(Describe)*
BloodSTOP iX Battle Matrix is indicated for external temporary control of minor to moderate bleeding of traumatic wounds.

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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"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."

510(k) Summary:

1. Submitter/510(k) Owner:

LifeScience PLUS, Inc.
2520A Wyandotte Street
Mountain View, CA 94043

Contact Person: Audrey Vitale
Telephone: 650-565-8172
Fax: 650-336-1130
Date prepared: June 29, 2016

2. Device:

Device Proprietary Name: BloodSTOP iX Battle Matrix
Device Common Name: Hemostatic Dressing
Classification: Unclassified
Classification Name: Dressing
Product Code: FRO

3. Predicate Devices:

- Primary: K072474 QuikClot eX (also marketed as QuikClot Combat Gauze)
- K072681 BloodSTOP iX Hemostatic Gauze

4. Device Description:

BloodSTOP iX Battle Matrix is a biocompatible, non-irritating, woven matrix of fibers made from cellulose. Using a proprietary process, regenerated cellulose is etherified and oxidized to make a water-soluble, hemostatic matrix. When applied to a wound, **BloodSTOP®** iX Battle Matrix absorbs blood and other body fluids, transforms into a gel, actively aids in blood coagulation, and adheres to the wound with a protective translucent layer. BloodSTOP iX exerts its pro-coagulant activity by activating the intrinsic coagulation pathway, accelerating clot formation. Its water solubility allows for easy removal through rinsing without disruption of the clotted wound surface. BloodSTOP iX Battle Matrix is provided sterile in a simple to use format that readily conforms to a wound: 3”x24” strip, z-folded to an 8-layer 3”x3” pad.

5. Indications For Use:

BloodSTOP iX Battle Matrix is indicated for external temporary control of minor to moderate bleeding of traumatic wounds.

6. Technological Characteristics and Substantial Equivalence:

Two predicate devices have been selected to support substantial equivalence of BloodSTOP iX Battle Matrix:

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www.lifescienceplus.com

a) QuikClot eX (K072474, also marketed as QuikClot Combat Gauze): same intended use and similar technological characteristics.

BloodSTOP iX Battle Matrix and QuikClot eX (Combat Gauze) have the same intended use: temporary external use for the control of bleeding of traumatic wounds.

BloodSTOP iX Battle Matrix is technologically similar to the predicate device QuikClot eX (Combat Gauze) in design in that both products are in presented in an intuitive, easy-to-use, single-use, sterile, dressing format that readily conforms to a wound. Both are free of animal-derived components. They have the same principle of operation in that, when applied to a wound with pressure, they exert hemostatic action to control bleeding. BloodSTOP iX Battle Matrix, upon contact with blood, transforms into a gel, adheres to the wound, and activates the intrinsic coagulation pathway, accelerating clot formation. The mechanism of QuikClot eX (Combat Gauze), containing the hemostatic mineral agent kaolin in a gauze matrix, is similar: when contacting blood, it initiates the clotting process by activating the intrinsic coagulation pathway.

The products are technologically different in hemostatic agent. In QuikClot eX, the agent is kaolin mineral powder. With BloodSTOP iX Battle Matrix, the etherified, oxidized, regenerated cellulose matrix itself initiates hemostasis. Although the hemostatic components of these two products are different, their mechanism of action and outcome is substantially similar.

b) BloodSTOP iX Hemostatic Gauze (K072681): similar intended use and same technological characteristics

BloodSTOP iX Battle Matrix and BloodSTOP iX Hemostatic Gauze have similar indication statements as both are for temporary external use to control surface bleeding. The intended use of BloodSTOP iX Battle Matrix also includes bleeding of traumatic wounds.

BloodSTOP iX Battle Matrix and BloodSTOP iX Hemostatic Gauze are identical in format and chemical composition, both being etherified, oxidized, regenerated cellulose dressings produced by LifeScience PLUS, Inc., in the identical manufacturing process. BloodSTOP iX Battle Matrix is larger in size.

7. Performance Data

Performance testing included in this submission demonstrates that BloodSTOP iX Battle Matrix is as safe and as effective as the legally marketed predicates:

- Biocompatibility testing for the intended body contact and duration
- In-vivo testing in a severe bleed wound model

a) Biompatibility Testing

Biocompatibility testing recommended in ISO 10993-1 and additional tests recommended in FDA Blue Book Memo, G95-1, for evaluation of devices in contact with breached or compromised surfaces for a limited duration, were undertaken for BloodSTOP iX products. Test results demonstrate BloodSTOP iX Battle Matrix safety in that it is biocompatible for the intended use:

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Test	Result
Cytotoxicity	Non-cytotoxic
Intracutaneous Reactivity	Non-irritating
Sensitization/Hypersensitivity	Non-sensitizing
Primary Skin Irritation	Non-irritating
Systemic Injection, Acute Systemic Toxicity	Non-toxic
Systemic Injection, Subchronic/ Chronic Toxicity	Non-toxic
Subcutaneous Implantation	Non-reactive

b) Hemostatic Efficacy

In vivo testing demonstrates the safety and efficacy of BloodSTOP iX Battle Matrix for the intended use, using a widely recognized 6mm femoral artery injury model in swine. The results demonstrate that the new device is as safe and as effective as QuikClot eX (Combat Gauze) in achieving hemostasis as measured by time to hemostasis, blood loss, maintenance of MAP, 3-hour survival, hematological measures of clot formation, clot stability in simulated walking test, and absence of conclusive distant adverse effects.

8. Conclusion

BloodSTOP iX Battle Matrix has the same intended use as QuikClot eX (Combat Gauze) and is similar in technological characteristics. Both products are sterile wound dressings, a widely and intuitively used format. They are applied and removed in the same way and have the same principle of operation. The difference in technological characteristics is in the hemostatic agent. BloodSTOP iX Battle Matrix has been shown to be equivalently biocompatible for the contact and duration, to achieve equivalent (or better) hemostasis in every measure evaluated in the benchmark animal model, with equivalent clot stability during animal movement. In an abundance of caution, labeling contains a warning about potential risk of embolism in areas of exposed vasculature.

BloodSTOP iX Battle Matrix has a similar intended use and the same technological characteristics as BloodSTOP iX Hemostatic Gauze.

BloodSTOP iX Battle Matrix is substantially equivalent to the predicate devices based on technological characteristics and performance data including bench, pre-clinical and usability testing.

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