May 13, 2026

Alexander Bohorquez
Senior Regulatory Affairs Specialist
1600 W. Merit Pkwy.
South Jordan, Utah 84095

Re: K254073
Trade/Device Name: StatSeal Disc
Regulatory Class: Unclassified
Product Code: QSY
Dated: April 10, 2026
Received: April 13, 2026

Dear Alexander Bohorquez:

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,

MUSTAFA A. MAZHER -S

For 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

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)*
K254073

Device Name
StatSeal Disc

Indications for Use *(Describe)*

StatSeal Disc is intended for use by or on the order of a healthcare professional for external temporary control of bleeding from percutaneous needle access, vascular access sites, and percutaneous catheters.

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
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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

K254073

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

I. SUBMITTER

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095,
USA
+1.801.253.1600
Fax: N/A

Contact Person: Alexander Bohorquez
Date Prepared: December 19, 2025

II. DEVICE

Device Trade Name:	StatSeal Disc
Classification Name:	Unclassified
Regulation:	Unclassified
Regulatory Class:	Unclassified
Device Panel:	General & Plastic Surgery
Product Code:	QSY

III. PREDICATE DEVICE

Predicate Manufacturer:	Biolife, LLC
Predicate Trade Name:	StatSeal Disc
Predicate 510(k):	K130324

IV. DEVICE DESCRIPTION

StatSeal Disc is a single use compressed topical powder disc, primarily comprised of a hydrophilic polymer and potassium ferrate. The product achieves its principle intended action (hemostasis) by creating a physical barrier or seal to the blood flow. A foam backing is attached as an ancillary component to hold the disc in place and does not contact the wound. StatSeal Products are packaged in a foil pouch and sterilized with gamma radiation.

V. INDICATIONS FOR USE

Rx:

StatSeal Disc is intended for use by or on the order of a healthcare professional for external temporary control of bleeding from percutaneous needle access, vascular access sites, and percutaneous catheters.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device to demonstrate substantial equivalence:

	StatSeal Disc (Subject Device)	**StatSeal Disc – K130324**	**Justification of Differences**
Indications for Use	**Rx:** StatSeal Disc is intended for use by or on the order of a healthcare professional for external temporary control of bleeding from percutaneous needle access, vascular access sites, and percutaneous catheters.	**OTC:** *StatSeal Disc* is intended for **OTC** use as a topical dressing for bleeding control associated with minor wounds, for temporary external control of minor bleeding from minor wounds, minor cuts, minor lacerations and minor burns. **Rx:** *StalSeal Disc* is intended under the care of a health care professional for external temporary control of bleeding from percutaneous needle access,vascular access sites and percutaneous catheters.	**Same**
Materials	Potassium Ferrate, Hydrophilic Polymer, Magnesium Stearate	Potassium Ferrate, Hydrophilic Polymer	Same; subject device added magnesium stearate for processing aid in manufacturing

Design	Powder pressed into a Disc	Powder pressed into a Disc	Subject and predicate K130324 are same
Sterile	Yes	Yes	Same
Mechanism of Action	StatSeal Disc stops bleeding & exudate from minor external wounds and procedures. It achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood.	StatSeal Disc stops bleeding & exudate from minor external wounds and procedures. It achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood.	Same

	StatSeal Disc is not biologically derived and is non-toxic.	StatSeal Disc is not biologically derived and is non-toxic.	
Shelf-Life	16 months	2 years	Subject device currently has 16-month shelf-life

VII. Non-Clinical Testing

PERFORMANCE DATA

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

Sterilization & Shelf-life Testing: StatSeal Discs are sterile devices intended for single use.

High Pressure Pneumatic Testing

Vascular Access Hemostasis Properties of StatSeal Test Articles in Swine.

BIOCOMPATABILITY TESTING

The biocompatibility evaluation for the StatSeal Disc with magnesium stearate was conducted in accordance with the FDA guidance document: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

- Cytotoxicity
- Sensitization
- Irritation
- Implantation
- Pyrogenicity
- Biological Evaluation and Toxicological Risk Assessment

The StatSeal Disc with magnesium stearate met the biocompatibility requirements for a surface contacting device where the disc product contacts breached or compromised skin with prolonged exposure (> 24hr- 30days).

CLINICAL TESTING

Clinical testing was not provided.

VIII. CONCLUSIONS

StatSeal Disc with magnesium stearate has the same intended use as the predicate StatSeal Disc (K130324) device. StatSeal Disc with magnesium stearate raises no new issues of safety or effectiveness. The conclusions drawn from the non-clinical testing demonstrate that the device is as safe and effective as the legally marketed StatSeal Disc, K130324.