April 8, 2022

Merit Medical Systems, Inc.
Sari Stevens
Senior Regulatory Affairs Specialist
1600 W Merit Parkway
South Jordan, Utah 84095

Re: K212882
Trade/Device Name: SCOUT BX Delivery System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: September 8, 2021
Received: September 10, 2021

Dear Sari Stevens:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Deborah Fellhauer, RN, BSN
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212882

Device Name
SCOUT Bx Delivery System

Indications for Use *(Describe)*
Using SCOUT Bx Delivery System, the SCOUT Reflector is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SCOUT System) the SCOUT Reflector is located and surgically removed with the target tissue. The SCOUT System is intended only for the non-imaging detection and localization of the SCOUT Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

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.

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510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4674 Sandeep Saboo 04/01/2022 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	SCOUT Bx™ Delivery System Implantable Chip Marker, Radiographic, Implantable 2 NEU 878.4300 General & Plastic Surgery
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	SCOUT Surgical Guidance System Marker, Radiographic, Implantable K181007 Merit Medical Systems, Inc.
Reference Device	No reference devices were used in this submission.	
Device Description	The SCOUT Bx Delivery System (including the SCOUT Reflector) is a sterile, single use device composed of a SCOUT Reflector preloaded in a delivery system. The SCOUT Reflector, when used in conjunction with the SCOUT Handpiece and SCOUT Console, can be used as a guide for the surgeon to follow in the excision of tissue. The SCOUT Reflector is visible using ultrasound and radiography. The SCOUT® Console, SCOUT Handpiece and SCOUT Reflector are components of the SCOUT Surgical Guidance System. The SCOUT Bx Delivery System is intended to be used with compatible Hologic® Biopsy Devices (Eviva® 0913-20, Eviva 1213-20, BREV09 (20mm aperture) and ATEC® ILS 0914-20).	
Indications for Use	Using SCOUT Bx Delivery System, the SCOUT Reflector is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SCOUT System) the SCOUT Reflector is located and surgically removed with the target tissue. The SCOUT System is intended only for the non-imaging detection and localization of the SCOUT Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.	
Comparison to Predicate Device	The SCOUT Bx Delivery Device has the similar design and technological characteristics as the predicate SCOUT Delivery Device. Both devices are used with the SCOUT Surgical Guidance System to implant the SCOUT Reflector to the target tissue. The subject device differs from the predicate device in. • Blunt cannula compared to the sharp cannula	

	• No depth marks on the blunt cannula • Compatible with legally marketed 3rd party biopsy devices • Plunger for deployment instead of a trigger • Allows for Stereotactic (X-ray) and MRI deployment imaging instead of X-ray and ultrasound imaging • Longer Length • Change in grade of stainless steel for tube and plunger • Change in non-patient contacting materials in device handle • 15G instead of 16G • Indications for Use statement has minor updates due to updated branding and readability; removal of word "SAVI", capitalization of "SCOUT", moved "(>30 days)" from after word "mark" to after "tissue" The comparison between the subject and reference devices is based on the following: • Same intended use • Same Indications for Use • Same sterilization methods • Same fundamental technology/principle of operation between the subject and predicate devices
Performance Data	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject SCOUT Bx Delivery System was conducted based on the risk analysis and based on the requirements of the following international standard: • ISO 7864 Fourth edition 2016-08-01, Sterile hypodermic needles for single use - Requirements and test methods • ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods • JIS T 3228, Biopsy needles for single use • ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization • ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity • USP 43-NF38:2020 <151> Pyrogen Test • ISO 11607-1: 2019, Packaging for terminally sterilized medical devices • ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems • EN ISO 2233: 2001 - Packaging - Complete, Filled Transport Packages and Unit Loads - Conditioning for Testing • ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]

	• ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. • ASTM F88-15, Standard Test Method for Seal Strength of Flexible Barrier Materials The following performance data were provided in support of the substantial equivalence determination. **Biocompatibility testing** The biocompatibility evaluation for the SCOUT Bx Delivery System was conducted in accordance with ISO 10993-1:2018. The battery of testing included the following tests: • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity The SCOUT Bx Delivery System is considered tissue contacting for a duration of less than 24 hours.
Performance Data cont.	<u>Performance Testing-Bench</u> • Compatibility with legally marketed 3rd party Biopsy Device • Deployment Accuracy • Cannula Effective Length & OD • Plunger to Handle Tensile • Plunger to Rod Tensile • Handle to Cannula Tensile • Resistance to Corrosion • Design Validation • Packaging Qualification No clinical or pre-clinical testing was conducted to evaluate the substantial equivalence of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject SCOUT Bx Delivery System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the SCOUT Delivery System, cleared as part of the SCOUT Surgical Guidance System (K181007).