



February 12, 2024

Merit Medical System, Inc.
Saboo Sandeep
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K231468

Trade/Device Name: SCOUT MD Surgical Guidance System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 19, 2023
Received: May 22, 2023

Dear Saboo Sandeep:

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.

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

Digitally signed by Tek
N. Lamichhane -S
Date: 2024.02.12
07:53:58 -05'00'

Tek Lamichhane, Ph.D.

Assistant Director

DHT4B: Division of Infection Control
and 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)

K231468

Device Name

SCOUT MD Surgical Guidance System

Indications for Use (Describe)

The SCOUT MD 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 MD System) the SCOUT MD Reflector is located and surgically removed with the target tissue. The SCOUT MD System is intended only for the non-imaging detection and localization of the SCOUT MD 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.

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SCOUT MD Surgical Guidance System

Traditional 510(k) Premarket Notification

510(k) Summary-K231468

General Provisions

Submitter Name: Merit Medical Systems, Inc.
Address: 1600 West Merit Parkway
South Jordan, UT 84095
Telephone Number: (510) 468-9995
Contact Person: Sandeep Saboo
Date of Preparation: 02 February 2024
Registration Number: 1721504

Subject Device

Trade Name: SCOUT MD Surgical Guidance System
Common/Usual Name: Implantable Clip
Classification Name: Marker, Radiographic, Implantable

Predicate Device

Trade Name: SAVI Scout Reflector and SAVI Scout System
Classification Name: Marker, Radiographic, Implantable
Premarket Notification: K181007
Manufacturer: Merit Medical Systems, Inc.
Predicate has not been a subject of a design related recall.

Classification

Class: Class II
Regulation: 21 CFR 878.4300
FDA Product Code: NEU
Review Panel: General & Plastic Surgery

Intended Use/Indications For Use

The SCOUT MD 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 MD System) the SCOUT MD Reflector is located and surgically removed with the target tissue. The SCOUT MD System is intended only for the non-imaging detection and localization of the SCOUT MD Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

SCOUT MD Surgical Guidance System

Traditional 510(k) Premarket Notification

Device Description

The SCOUT MD Surgical Guidance System consists of the following components:

- SCOUT MD Delivery System, which includes two components:
 - o SCOUT MD Reflector
 - o SCOUT MD Delivery Device
- SCOUT MD Guide
- SCOUT MD Handpiece
- SCOUT MD Console

The SCOUT MD Delivery System is used to implant the preassembled SCOUT MD Reflector. The needle of the Delivery System is percutaneously advanced into tissue to the site to be marked for biopsy or surgical removal. Needle placement is confirmed under imaging technique (radiographic, ultrasound). The Reflector (tissue marker) is deployed at the target site and the Delivery Device is removed from the patient and discarded. The Reflector, a passive implant, remains in situ and, if surgical removal of the target tissue is necessary, the Reflector is located at the time of surgery (intraoperatively) by the SCOUT MD Surgical Guidance System. The SCOUT MD Guide/Handpiece connected to the SCOUT MD Console is used to detect the SCOUT MD Reflector but it does not contact tissue. SCOUT MD Guides are always used while inside the SCOUT Guide Sheath. When the SCOUT MD System detects the Reflector, the Console emits audible feedback that increases in cadence as the Guide is placed closer to the Reflector. The distance between the distal end of the Guide and the detected Reflector, in millimeters, is displayed on the Console. If necessary, the Reflector is removed from the patient during a subsequent surgical procedure along with the tissue of interest or the Reflector can be left in-situ.

Comparison to Predicate

When compared to the predicate device (SAVI Scout System), the SCOUT MD Surgical Guidance System:

- Has the same indications for use;
- Has the same intended use;
- Has the same mechanism of action and principles of operation.

The fundamental scientific technology, use and materials/design of the subject device, SCOUT MD Surgical Guidance System, are the same as those of the predicate SAVI Scout System. The principle of operation and mechanism of action are the same. As with the predicate device SAVI Scout System, the SCOUT MD Delivery System is used to implant the preassembled SCOUT MD Reflector while the SCOUT MD Guides/Handpieces and the SCOUT MD Console are used to detect the SCOUT MD Reflector.

Provided in the table below is a comparison of the subject and the predicate devices. Based on the comparison, the intended/indications for use and technological characteristics of the SCOUT MD Surgical Guidance System are substantially equivalent to the predicate device (SAVI Scout Reflector and SAVI SCOUT System cleared per K181007).

SCOUT MD Surgical Guidance System

Traditional 510(k) Premarket Notification

Device Type →	SUBJECT Device (K231468)	PREDICATE Device (K181007)	Result of Comparison
Manufacturer →	Merit Medical Systems, Inc.	Merit Medical Systems, Inc.	
Device Name →	SCOUT MD Surgical Guidance System	SAVI Scout Reflector and SAVI SCOUT System	
Class	II	II	No Difference
Regulation Name	Implantable Clip	Implantable Clip	No Difference
Regulation Number	878.4300	878.4300	No Difference
Product Code	NEU	NEU	No Difference
Product Code Description	Marker, Radiographic, Implantable	Marker, Radiographic, Implantable	No Difference
Indications for Use:	The SCOUT MD Reflector is intended to be placed percutaneously in soft tissue to mark (>30 days) 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 MD System) the SCOUT MD Reflector is located and surgically removed with the target tissue. The SCOUT MD System is intended only for the non-imaging detection and localization of the SCOUT MD Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.	The SAVI Scout Reflector is intended to be placed percutaneously in soft tissue to mark (>30 days) 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 (SAVI Scout System) the SAVI Scout Reflector is located and surgically removed with the target tissue. The SAVI Scout System is intended only for the non-imaging detection and localization of the SAVI Scout Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.	No Difference (other than product name)
SYSTEM COMPARISON			
Procedure(s) Used	Used in guided surgical removal of soft tissue (e.g. breast tumor and related tissue).	Used in guided surgical removal of soft tissue (e.g. breast tumor and related tissue).	No Difference
Use environment	Intra-operative, guided surgical procedure	Intra-operative, guided surgical procedure	No Difference
Patient population	Adult patient diagnosed with carcinoma who are medically eligible for tumor resection	Adult patient diagnosed with carcinoma who are medically eligible for tumor resection	No Difference
Tissue Type	Soft tissue, including breast	Soft tissue, including breast	No Difference
Principle of Operation (localization technique)	Implantable reflector (marker) used in conjunction with proprietary location detection system which measures relative strength of RF reflective energy and provides proximity/location and distance information to the user	Implantable reflector (marker) used in conjunction with proprietary location detection system which measures relative strength of RF reflective energy and provides proximity /location information to the user	Minor Difference

SCOUT MD Surgical Guidance System

Traditional 510(k) Premarket Notification

System components	<ul style="list-style-type: none"> • Reflector (marker) • Reflector Delivery System • Guide (handpiece) • Console 	<ul style="list-style-type: none"> • Reflector (marker) • Reflector Delivery System • Guide (handpiece) • Console 	No Difference
REFLECTOR COMPARISON (Reflector is a component of the Delivery System)			
How provided	Sterile, assembled within the Delivery System	Sterile, assembled within the Delivery System	No Difference
SAL	SAL 10 ⁻⁶	SAL 10 ⁻⁶	No Difference
Implant Duration	> 30 days	> 30 days	No Difference
Reflector body	<ul style="list-style-type: none"> • 4mm (length) x 1.3.mm (dia), • Loctite 3922 (Fully encases electronics) 	<ul style="list-style-type: none"> • 4mm (length) x 1.3.mm (dia), • Loctite 3922 (Fully encases electronics) 	No Difference
Reflector length (end to end)	<p style="text-align: center;">Two Length Options</p> <ul style="list-style-type: none"> • 12mm • 8mm 	12mm	Similar: A smaller Reflector is available to meet clinician needs.
Reflector tissue contacting materials	<ul style="list-style-type: none"> • Nitinol SE508, light oxide [ASTM F2063-D] • Loctite 3922 	<ul style="list-style-type: none"> • Nitinol SE508, light oxide [ASTM F2063-D] • Loctite 3922 	No Difference
Reflector shapes	Four (4)	One (1)	Similar: 4 unique shapes allow clinicians to distinguish when multiple marker(s) are implanted
Reflector activity	Responsive (in presence of IR light) marker; passive marker (in absence of IR light)	Responsive (in presence of IR light) marker; passive marker (in absence of IR light)	No Difference
Reflector visibility	Visible under radiography, MR and ultrasound	Visible under radiography, MR and ultrasound	No Difference
DELIVERY SYSTEM COMPARISON (see above for comparison of Reflector, a component of the Delivery System)			
How provided	Sterile (SAL ≥ 10 ⁻⁶)	Sterile (SAL ≥ 10 ⁻⁶)	No Difference
Use	Single-use	Single-use	No Difference
Sterilization Method	EO	EO	No Difference
MR Compatibility	MR Unsafe	MR Unsafe	No Difference

SCOUT MD Surgical Guidance System

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Delivery of Reflector	Needle delivery system for percutaneous placement of Reflector (marker)	Needle delivery system for percutaneous placement of Reflector (marker)	No Difference
Working Length	5cm, 7.5cm and 10cm	5cm, 7.5cm and 10cm	No Difference
GUIDE/HANDPIECE COMPARISON			
How provided	Non-sterile for Reuse and Sterile, Single-Use Configurations	Non-sterile for Reuse and Sterile, Single-Use Configurations	No Difference
Primary functions	<ul style="list-style-type: none"> Receives micro impulse radar signal (RF electromagnetic wave signals) from Console. Delivers RF electromagnetic wave signal and infrared light pulses to soft tissue. Receives reflected signal back from the detected Reflector and transmits data to the connected Console. 	<ul style="list-style-type: none"> Receives micro impulse radar signal (RF electromagnetic wave signals) from Console. Delivers RF electromagnetic wave signal and infrared light pulses to soft tissue. Receives reflected signal back from the detected Reflector and transmits data to the connected Console. 	No Difference
Guide Handpiece Length	Handpiece Length: 140 mm length	Handpiece Length: 140 mm length	No Difference
Guide/Console interface	Cable	Cable	No Difference
Cables	<ul style="list-style-type: none"> Flexible, instant signal processing Tether probe to surgical Field 	<ul style="list-style-type: none"> Flexible, instant signal processing Tether probe to surgical Field 	No Difference
CONSOLE COMPARISON			
Console calibration	At Factory	At Factory	No Difference
Reflector Localization	<ul style="list-style-type: none"> Delivers micro impulse radar signal (RF electromagnetic wave signals) to Guide. Provides power to the Guide to enable Guide to output infrared light. Receives reflected RF electromagnetic wave signal from the Reflector through the Guide. The time delay between the transmitted signal and the true reflected signal is used to determine the distance between the distal surface of the Guide Handpiece and the Reflector. 	<ul style="list-style-type: none"> Delivers micro impulse radar signal (RF electromagnetic wave signals) to Guide. Provides power to the Guide to enable Guide to output infrared light. Receives reflected RF electromagnetic wave signal from the Reflector through the Guide. The time delay between the transmitted signal and the true reflected signal is used to determine the distance between the distal surface of the Guide Handpiece and the Reflector. 	No Difference
User interface	Touchscreen Display with volume control, start/stop, mode selection	LCD Display. Separate buttons for volume control, start/stop	Minor Difference
Audible location information (Cadence)	Higher click rate = closer proximity to site of Reflector (marker)	Higher click rate = closer proximity to site of Reflector (marker)	No Difference

SCOUT MD Surgical Guidance System

Traditional 510(k) Premarket Notification

Distinct Audible location information (Tone)	Provides for all compatible Reflectors (up to four) unique click tones	Provides for a single-compatible Reflector a unique click tone.	No Difference
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The following performance data have been provided in support of the substantial equivalence determination.

Safety & Performance Tests

- **Software Verification and Validation Testing** performed per IEC 62304 and documentation provided per FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”
- **Other Tests** were performed per approved test protocols which included:
 - Integrity: System withstands operating pressures
 - Functional Testing: Deployment, detection, accuracy
 - Dimensional Inspection and Testing: For each component of the system
 - Functional Testing for each component of the system and the entire system
 - Simulated Use: Deployment and detection test
 - MR Compatibility Testing per ASTM F2503
 - Biocompatibility Evaluation per ISO 10993-1
 - Sterilization Validation per ISO 11135
 - Packaging Validation per ASTM D4169
 - Accelerated Aging per ASTM F1980
 - Electrical Safety & EMC: In accordance with IEC 60601-1 and IEC 60601-1-2

The results of safety and performance tests demonstrate that the SCOUT MD Surgical Guidance System (subject device) is substantially equivalent to the predicate device (SAVI Scout Reflector and SAVI Scout System cleared per K181007).

Summary of Substantial Equivalence

Based on the comparison of intended/indications for use and technological characteristics, the subject device is substantially equivalent to the predicate device. The performance tests for each system component and the hardware and software verification and validation testing demonstrate that the subject device meets its performance specifications and will perform as intended in the specified use conditions and that any differences between the subject device and predicate device do not raise new questions of safety and effectiveness. Therefore, the subject device can be found to be substantially equivalent to the predicate device (SAVI Scout Reflector and SAVI Scout System cleared per K181007).