December 19, 2025

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

Re: K252892
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: September 10, 2025
Received: September 11, 2025

Dear Sandeep Saboo:

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.

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252892

Please provide the device trade name(s).

SCOUT MD Surgical Guidance System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:	**K252892**

510(k) Summary

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: 17 December 2025 Registration Number: 1721504
Subject Device	Trade Name: SCOUT MD Surgical Guidance System Common/Usual Name: Implantable Clip Classification Name: Marker, Radiographic, Implantable
Primary Predicate Device	Trade Name: SCOUT MD Surgical Guidance System Classification Name: Marker, Radiographic, Implantable Premarket Notification: K231468 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 (> 30days) 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.

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 Single-Use 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 used with sterile SCOUT Guide Sheath and/or sterilized per the instructions in the IFU. When the SCOUT MD System detects the Reflector, the Console emits audible feedback that increases in cadence as the Guide/Handpiece is placed closer to the Reflector. The distance between the distal end of the Guide/Handpiece 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 SCOUT MD Surgical Guidance System cleared per K231468, the subject device: • Has the same indications for use; • Has the same intended use; • Has the same mechanism of action and principles of operation, mechanism of action, fundamental scientific technology, materials of construction and device design. 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 primary predicate device. The subject 510(k) adds MR Conditional claim on labeling and adds the reprocessing instructions for VHP sterilization by the end user.

Device Type→	**SUBJECT Device**	**PREDICATE Device (K231468)**	**Result of Comparison**
Manufacturer→	**Merit Medical Systems, Inc.**	**Merit Medical Systems, Inc.**	
Device Name →	**SCOUT MD Surgical Guidance System**	**SCOUT MD Surgical Guidance System**	
Class	**II**	**II**	SAME

Device Type→	SUBJECT Device	PREDICATE Device (K231468)	Result of Comparison
Manufacturer→	**Merit Medical Systems, Inc.**	**Merit Medical Systems, Inc.**	
Device Name →	**SCOUT MD Surgical Guidance System**	**SCOUT MD Surgical Guidance System**	
Regulation Name	**Implantable Clip**	**Implantable Clip**	SAME
Regulation Number	**878.4300**	**878.4300**	SAME
Product Code	**NEU**	**NEU**	SAME
Product Code Description	**Marker, Radiographic, Implantable**	**Marker, Radiographic, Implantable**	SAME
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.	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.	SAME
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).	SAME
Use environment	Intra-operative, guided surgical procedure	Intra-operative, guided surgical procedure	SAME
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	SAME
Tissue Type	Soft tissue, including breast	Soft tissue, including breast	SAME
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 and distance information to the user	SAME

System components	• Reflector (marker) • Reflector Delivery System • Guide (handpiece) • Console	• Reflector (marker) • Reflector Delivery System • Guide (handpiece) • Console	SAME
REFLECTOR COMPARISON (Reflector is a component of the Delivery System)			
How provided	Sterile, assembled within the Delivery System	Sterile, assembled within the Delivery System	SAME
SAL	10^{-6}	10^{-6}	SAME
Implant Duration	> 30 days	> 30 days	SAME
Reflector body	• 4mm (length) x 1.3.mm (dia), • Loctite 3922 (Fully encases electronics)	• 4mm (length) x 1.3.mm (dia), • Loctite 3922 (Fully encases electronics)	SAME
Reflector length (end to end)	Two Length Options • 12mm • 8mm	Two Length Options • 12mm • 8mm	SAME
Reflector tissue contacting materials	• Nitinol SE508, light oxide [ASTM F2063-D] • Loctite 3922	• Nitinol SE508, light oxide [ASTM F2063-D] • Loctite 3922	SAME
Reflector shapes	Four (4)	Four (4)	SAME
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)	SAME
Reflector visibility	Visible under radiography, MR and ultrasound	Visible under radiography, MR and ultrasound	SAME
DELIVERY SYSTEM COMPARISON (see above for comparison of Reflector, a component of the Delivery System)			
How provided	Sterile	Sterile	SAME
SAL	10^{-6}	10^{-6}	SAME
Use	Single-use	Single-use	SAME
Sterilization Method	EO	EO	SAME
MR Compatibility	MR Conditional	MR Unsafe	MODIFIED
Delivery of Reflector	Needle delivery system for percutaneous placement of Reflector (marker)	Needle delivery system for percutaneous placement of Reflector (marker)	SAME
Working Length	5cm, 7.5cm and 10cm	5cm, 7.5cm and 10cm	SAME
GUIDE/HANDPIECE COMPARISON			
How provided	Non-sterile for Reuse and Sterile, Single-Use Configurations	Non-sterile for Reuse and Sterile, Single-Use Configurations	SAME

Reprocessing Methods	Manual, wipe-based cleaning and Disinfection Sterilization in STERRAD 100S, NX and NX100 systems	Manual, wipe-based cleaning and Disinfection No Sterilization option provided.	MODIFED
Primary functions	• 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.	• 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.	SAME
Guide Handpiece Length	Handpiece Length: 140 mm length	Handpiece Length: 140 mm length	SAME
Guide/Console interface	Cable	Cable	SAME
Cables	• Flexible, instant signal processing • Tether probe to surgical Field	• Flexible, instant signal processing • Tether probe to surgical Field	SAME
CONSOLE COMPARISON			
Console calibration	At Factory	At Factory	SAME
Reflector Localization	• 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.	• 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.	SAME
User interface	Touchscreen Display with volume control, start/stop, mode selection	Touchscreen Display with volume control, start/stop, mode selection	SAME
Audible location information (Cadence)	Higher click rate = closer proximity to site of Reflector (marker)	Higher click rate = closer proximity to site of Reflector (marker)	SAME
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.	SAME

Safety & Performance Tests	The following performance data have been provided in support of the substantial equivalence determination. • **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: o Integrity: Device functional testing post reprocessing o Functional Testing of SCOUT MD Guides and SCOUT Console o MR Compatibility Testing per ASTM F2503 o Biocompatibility Evaluation per ISO 10993-1. o Sterilization Validation per ISO 22441. o 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 devices.
Summary of Substantial Equivalence	The SCOUT MD Surgical Guidance System has the same Intended Use as the predicate device (K231468). The subject and the primary predicate devices are identical, apart from the changes proposed related to (re)sterilization of the Guides in STERRAD 100S, NX and NX100 systems, MR Conditional claim added to delivery system. These changes do not impact substantial equivalence, therefore, the devices can be considered to be substantially equivalent.