1/21/2023

Endomagnetics Ltd
Mehryar Behizad
Regulatory Director
330 Cambridge Science Park, Milton Road
Cambridge, Cambridgeshire CB4 0WN
United Kingdom

Re: K222832
Trade/Device Name: Sentimag System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: December 19, 2022
Received: December 20, 2022

Dear Mehryar Behizad:

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,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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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)*
K222832

Device Name
Sentimag System

Indications for Use *(Describe)*
The Sentimag Magnetic Localization System when used with the Magseed® marker is indicated to assist in localizing soft tissue lesions.
The Endomag Sentimag System is the only non-imaging guidance system intended for use with the Magseed® magnetic marker.

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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510(k) SUMMARY

SUBMITTER INFORMATION

Submitter's Name:	Endomagnetics Ltd.
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Contact Person:	Mehryar Behizad PhD Regulatory Director
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Email:	mbehizad@endomag.com
Date summary prepared:	25th August 2022

DEVICE INFORMATION

Trade name:	Sentimag System
Common name:	Gen 3
Classification name:	Marker, Radiographic Implantable
Regulation:	21 CFR 878.4300
Device Classification:	Class II
Product Code:	NEU

PREDICATE DEVICE

- Principal Predicate K153044 Sentimark Magnetic Marker System
- Secondary Predicate K173587 Magseed® Magnetic Marker System
-Tertiary Predicate is Special 510(k) K163541 Magseed® Magnetic Marker System

The rationale for the ranking of the predicates is as follows:

The Principal Predicate is K153044. This Traditional 510(k) submission describes the SentiMark magnetic marker in conjunction with Sentimag. This system is used to mark and locate soft tissue for surgical removal. It describes the indication and the magnetic mechanism of detection and that the Sentimag detector is the unit that induces and detects the magnetic response in the Magseed magnetic marker. Magseed marker in combination with Sentimag (Gen 2) has been legally marketed in the United States since its 510(k) clearance on 2nd March 2016.

The Secondary Predicate is K173587. This has been identified as the second most important predicate because this is a derivative predicate that describes the use of the same system (Sentimag/Magseed). However, in this predicate, data for implantation of Magseed for more than 30 days was presented, reviewed and cleared by the FDA (16 February 2018).

The target tissue, magnetic mode of detection and materials of construction are exactly the same as the primary predicate. The overall indication (marking, detection and removal of soft tissue) remained the same as the Principal Predicate, but the extended duration to more than 30 days for the Magseed marker implantation was approved. This has no bearing on the Sentimag Gen 2 detector.

The Tertiary Predicate is Special 510(k) K163541. This Premarket Submission is solely concerned with the change of name for the marker from SentiMark to Magseed. There is no revision to the implanted marker and it has no bearing on the Sentimag Gen 2 detector. This was cleared on 13th January 2017.

DESCRIPTION OF DEVICE

The Sentimag Gen 3 System is the 3rd generation of Sentimag detector, intended for the non-imaging detection and localization of Magseed® magnetic marker that has been implanted in a lumpectomy site intended for surgical removal. It consists of a base unit and a probe.

This generation of the device has two modes:

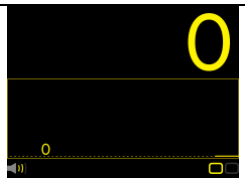
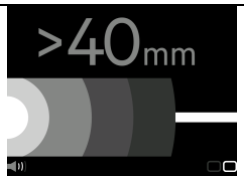
a) Counts Mode: This mode is the exact equivalent of the current generation of the Sentimag detector (Sentimag Gen 2 - described in K153044). In this mode Magseed (K173587) and is detectable based on a counts signal displayed on the base unit of Sentimag device.

b) Measure Mode: **Please note that this mode has a different graphic display and is currently dormant in Sentimag Gen 3**

Risk control measures in relation to users wrongly using Sentimag Gen 3 in Measure mode are outlined in Risk Management File: Use risk Analysis Appendix 1, line U 6.4.

Briefly these are:

a) Magseed does not provide a clinically usable signal with Measure mode,
b) The displays from the two modes are visually clearly distinguishable. Counts mode looks very similar to the Gen2 display with yellow graphics, while Measure mode is graphically very different and in a grey color (initially) as shown from the screen shots of the initial 'ready to use' display below:

Gen 2	Gen3 Counts mode	Gen3 Measure mode
		

Initial 'Ready to use' screenshots from the Gen2 and Gen3 Sentimag displays

c) The Gen 3 system remembers which mode was previously selected when it is next used, so once set in Counts mode, users would not have any need to change modes.
d) Specific training will be provided to ensure end users use Sentimag Gen 3 system in the correct mode.
e) The IFU will provide explicit direction in relation to not using the Measure mode in addition to the above.

Note: Other components of risk management file are enclosed as part of this submission.

The probability of end users utilising Sentimag Gen 3 in the inappropriate mode has been minimised through a series of risk control measures outlined in Use risk analysis, Appendix 1, lines U 6.4.

Whilst we recognize that there is the possibility that end users might accidentally switch to measure mode, we believe the visual difference, lack of signal and suitable training, would ensure the use of the appropriate mode. End users are trained to seek a signal before commencing surgery, so as to make sure the system is fully operational. Existing end users are familiar with counts mode through their use with Gen 2 and new users would be trained to use only this mode for the Magseed, and provided with instruction via the IFU.

The predicate for the Sentimag Gen 3 device is the previous generation of the detector and was introduced in previous submissions to the FDA as Sentimag but in fact was the second generation in this family of devices. So, throughout this submission in order to distinguish between the predicate detector and the detector which is the subject of this submission the predicate will be referred to as “Sentimag Gen 2” and the detector in this submission will be referred to as “Sentimag Gen 3”.

Sentimag Gen 3 also supports a standard diameter and a thin probe. The functional performance of the two different probes is equivalent in the two different Gen 3 modes. In Counts mode both the probes are functionally equivalent to Sentimag (Gen 2) predicate.

The Sentimag System is designed for use in an operating room environment by suitably trained physicians who are experienced in diagnosis and treatment of breast lesions.
The Sentimag System aids the surgeon to detect surgically invasively magnetic marker material that has been placed for the purpose of detecting a non-palpable lesion, and to locate target excision sites.

Prior to a lumpectomy procedure, the Magseed® Magnetic Marker which already has clearance (K173587) is placed percutaneously into the breast, using imaging guidance such as ultrasound or radiography, to temporarily mark a site intended for surgical removal. During a surgical procedure, the hand-held Sentimag probe emits an alternating magnetic field that detects the magnetic response of the Magseed® magnetic marker, this signal is converted by the base unit into a visual and audible response that is similar in use to the predicate device.

The Sentimag Gen 3 device is the successor to the Sentimag Gen 2 device (Principal Predicate K153044, Secondary Predicate K173587 and Tertiary Predicate 510(k) K163541). In common with the principal predicate, Endomag Sentimag Gen 3 device is able to detect the Magseed Magnetic Marker using proximity detection based on susceptometry.

INTENDED USE

The Sentimag system is intended for intra-operative use, to help surgeons detect and locate magnetic marker in the body. The system is specifically intended to detect Magseed® implantable magnetic marker used to mark soft tissue lesions.
The Endomag Magseed® Magnetic Marker (K173587) is placed within the target soft tissue prior to planned surgical removal. The currently cleared Magseed marker (K173587), when used in conjunction with the Sentimag Gen 3 System in Counts mode, can be used as a guide for the surgeon to follow in the excision of tissue.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

As the predicate Sentimag Gen 2 detector (K153044), the Sentimag Gen 3 System utilizes non-imaging technologies that are comprised of a console that incorporates electronics and a simple user interface, plus a probe handpiece. Like the predicate (Sentimag Gen 2), Sentimag Gen 3 is a proximity detector. The Sentimag Gen3 System comprises of a mains-powered base unit, a detachable hand-held probe available in 2 sizes (Standard Probe and Thinner Probe) that is connected to the base unit with a flexible cable, and a detachable electronic footswitch that is connected to the base unit with a flexible cable. A single use sterile sheath is required to be placed over the probe prior to the procedure, this is to be supplied by the hospital.

The hand-held probe which emits an alternating magnetic field that detects the magnetic response of the marker. When the marker is exposed to a magnetic field it becomes magnetic, and this magnetism can then be detected using the probe which gives an audible and visual signal of the level of magnetism. In count mode this is in the format of a numerical reading. In this mode the Sentimag Gen 3 device can measure Magseed® in exactly the same way as the predicate (Sentimag Gen 2).

A location marker is placed percutaneously in situ at the clinical target site by a delivery system using 5 cm to 12 cm delivery systems described in predicates K173587 and K163541 and then the detector handpiece is used for the intraoperative detection and localization of the implanted marker. The handpiece is connected by a flexible cable to a console unit that provides the user with a visual indication of the presence and proximity of the marker.
In Counts mode Sentimag Gen 3 can detect Magseed® (K173587) in exactly the same way and with exactly the same sensitivity as the predicate (Sentimag Gen 2 - described in K153044). In common with the Sentimag Gen 2 predicate, in Sentimag Gen 3 in Count mode a visible numerical representation of the detected signal level is simultaneously displayed on the base unit's liquid crystal display.

Additionally, Sentimag Gen 3 supports a Measure Mode. **Please note that this mode is currently dormant in Sentimag Gen 3.**

In both Count mode and Measure mode the sensing of the magnetic signal is indicated by a change in pitch (frequency) of an audio output from the Sentimag base unit.

The Gen 3 Sentimag also provides an option for a thinner (13.5 mm diameter) probe. This probe functions in exactly the same way as a normal diameter (18.5 mm) probe in each mode described above.

DISCUSSION OF NON-CLINICAL TESTS SUBMITTED

Performance testing was conducted to evaluate and characterize the performance of the Sentimag System (Gen 3) with the previously approved Magseed® (K173587) Pre-clinical/Laboratory testing included:

- Usability testing of Sentimag (Gen 3)- Standard and thin probe
- Sensitivity testing of Sentimag (Gen 3) standard and thin probes against Magseed (K173587).
- Comparison of Sentimag (Gen 3) and Sentimag (Gen 2) sensitivity in counts mode
- Simulated Use of Sentimag (Gen 3) with Magseed (K173587) in Counts mode using the following simulated tissue:
    1. Liver
    2. Thyroid (CIRS Model 074)
    3. Breast (CIRS Model 073)
    4. Abdominal Tissue Plate (SynDaver 141720, 2N Std, 5mm Fat, 5mm muscle)
    5. Lung Model (SynDaver)

CONCLUSION

Endomagnetics believes that Sentimag System (K153044) is the predicate device because the Sentimag (Gen 3) is the same as the predicate Sentimag in Counts mode. The Measure mode in Sentimag Gen 3 is an additional function. **The Sentimag Gen3 Measure mode is currently dormant.**

Specific risk control measures have been adopted to prevent the end user from using this mode. These risk control measures are outlined in section 5.4 above. Sentimag Gen 3 has the same Intended Use and very similar technological characteristics to the predicate device.
The different technological characteristics do not raise any new questions of safety or effectiveness. The test, verification and validation data presented in this submission demonstrate substantial equivalence of the Sentimag Gen 3 to the predicate (Sentimag Gen 2).