June 28, 2024

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

Re: K232865
Trade/Device Name: Magseed Pro Magnetic Marker System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 30, 2024
Received: May 31, 2024

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 (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: 2024.06.28 12:10:06 -04'00'

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

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)*
K232865

Device Name
Magseed Pro Magnetic Marker System

Indications for Use *(Describe)*
The Endomag Magseed Pro Magnetic Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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-K232865

SUBMITTER INFORMATION

Submitter's Name:	Endomagnetics Ltd.
Address:	330 Cambridge Science Park, Milton Road Cambridge CB4 0WN United Kingdom
Contact Person:	Dr. Mehryar Behizad Regulatory Director
Tel:	+44 1223 652540
Email:	mbehizad@endomag.com
Date summary prepared:	26th June 2024

DEVICE INFORMATION

Trade name:	Magseed Pro Magnetic Marker System
Common name:	Tissue Marker, Marker Delivery System
Classification name:	Marker, Radiographic, Implantable
Regulation:	21 CFR 878.4300
Device Classification:	Class II
Product Code:	NEU

PREDICATE DEVICES

- Primary Predicate K173587 Magseed Magnetic Marker

- Secondary Predicate K073095 Tumark Professional tissue marker

DESCRIPTION OF DEVICE

The Endomag Magseed Pro Magnetic Marker is intended for use as a soft tissue marker. The marker is visible under ultrasound and radiographic imaging. It is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

The Magseed Pro Magnetic Marker is a sterile, single use device composed of a self-expanding four-sided tetrahedral nitinol structure, with side lengths of 6.3 mm with a magnetic core. The device is not inherently magnetic. It is capable of being magnetized and located by Endomagnetics' Sentimag Gen 2 or Gen 3 devices. The Magseed Pro Magnetic Marker comes preloaded in a 17-gauge needle delivery system.

The Magseed Pro Magnetic Marker is placed percutaneously into the tissue, using imaging guidance such as ultrasound or radiography, to mark a site intended for surgical removal. The Magseed Pro Magnetic Marker is subsequently localized by using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (Endomag Sentimag® Systems, Sentimag Gen 3 K222832 or Sentimag Gen 2 K153044). The marker can be detected up to 45 mm from the Sentimag® probe. The surgeon may use compression of the tissue with the probe to improve detection. The marker is located and surgically removed with the target tissue.

Additionally, Magseed Pro can be used in combination with Sentimag Gen 3 in Measure mode. When used in this modality, the distance between the location of Magseed Pro and the tip of the Sentimag Gen 3 probe can be measured. This distance is graphically displayed on the LCD screen of Sentimag Gen 3 in this mode.

INTENDED USE/INDICATIONS FOR USE

The Endomag Magseed Pro Magnetic Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

As with the primary predicate K173587, Magseed Pro is a soft tissue marker placed percutaneously at the clinical target site by a delivery system and then the detector handpiece is used for the intraoperative detection and localization of the implanted marker. Both the Magseed Pro Magnetic Marker and primary predicate are detected using the Sentimag detection system. The localisation system used in the primary predicate and the current device both work based on magnetic susceptometry.

In common with the secondary predicate, K073095**,** the tissue contacting part of the implanted Magseed Pro marker consists of Nitinol. Also in common with this predicate, Magseed Pro is self-expanding after deployment and can be implanted for more than 30 days.

In Counts Mode, the Sentimag Gen 3 system can detect any Endomag magnetic marker including the Magseed marker (predicate) and the Magseed Pro marker. This mode is the same as the predicate device which can detect a Magseed Marker from up to 30mm. The Sentimag Gen3 system additionally has Measure Mode which measures the distance from its probe tip to the Magseed Pro marker, providing a millimetre distance on the screen. The probe can detect this marker to a depth of up to 45 mm within soft tissue and provide a millimeter measurement up to 40mm.

Like both predicates, Magseed Pro can be detected by radiographic imaging modalities. The devices are delivered by conventional needle delivery systems of similar gauge (17G, Magseed Pro; 18G Magseed).

SUMMARY OF SAFETY AND PERFORMANCE TESTS SUBMITTED

Performance testing was conducted to evaluate and characterize the performance of the Magseed Pro Magnetic Marker when used with Sentimag (Gen 2 and Gen 3) Systems. This included:

- Dimensional verification
- Robustness testing
- Insertion, deployment and withdrawal force testing
- MRI Compatibility
- Biocompatibility testing per ISO 10993-1
- Corrosion testing
- Simulated use testing

SUMMARY OF CLINICAL TESTS SUBMITTED

Clinical performance testing was conducted in 60 patients to evaluate and characterize the performance of the Magseed Pro Magnetic Marker with Sentimag Gen 3 System in patients with breast cancer.

Clinical testing included:

- Efficacy – To provide evidence that the Magseed Pro marker can be successfully placed and retrieved- The primary end points are retrieval rates of Magseed Pro marker with the target region excised in specimen for breast/soft tissue lesions.
- Safety Endpoints-
    - Rate of device related Adverse Events (AE's or SAE's)
    - Presence of unexpected histological tissue responses

No device-related adverse events or unexpected tissue reactions were observed in any of the patients.

CONCLUSION

The Magseed Pro device has the same intended use and indication and similar technological characteristics to its predicates. The performance and safety testing conducted demonstrate that the Magseed Pro device is substantially equivalent to the predicate devices, Magseed (K173587) and Tumark Professional U (K073095), with equivalent safety and performance.

The Magseed Pro Magnetic Marker has the same Intended Use as the predicate devices. The different technological characteristics do not raise any new questions of safety or effectiveness. Therefore, the Magseed Pro Magnetic Marker System can be found to be substantially equivalent to the primary predicate device, Magseed K173587.