DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 16, 2018

Endomagnetics Ltd.
% Dr. Andrew Shawcross
Chief Operations Officer
The Jeffreys Building, Cowley Road
Cambridge, CB4 OWS United Kingdom

Re: K173587
Trade/Device Name: Magseed Magnetic Marker
Regulation Number: 21 CFR § 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code:
Dated: November 15, 2017
Received: November 20, 2017

Dear Dr. Shawcross:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173587

Device Name
Endomag Magseed® Magnetic Marker

Indications for Use *(Describe)*
The Endomag Magseed® 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.

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5 510(K) SUMMARY

5.1 SUBMITTER INFORMATION

Submitter's Name:	Endomagnetics Ltd.
Address:	The Jeffreys Building
	Cowley Road
	Cambridge
	CB4 0WS
	United Kingdom
Contact Person:	Andrew Shawcross
	Chief Operations Officer
Tel:	+44 1223 652540
Email:	ashawcross@endomag.com
Date summary prepared:	15 November 2017

5.2 DEVICE INFORMATION

Trade name:	Magseed Magnetic Marker
Common name:	Tissue Marker
Classification name:	Implantable Clip
Regulation:	21 CFR 878.4300
Device Classification:	Class II
Product Code:	NEU

5.3 PREDICATE DEVICES

1. Carbon Medical Technolgies, Inc. BiomarC Gold Tissue Marker (K070436).
2. Sentimag System, Sentimark (Magseed) Magnetic Marker System (K153044 & K163541)

5.4 DESCRIPTION OF DEVICE

The Endomag Magseed® Magnetic Marker is intended for use as a 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 Magnetic Marker is placed percutaneously into the tissue, using imaging guidance such as ultrasound or radiography, to mark a site that is for example intended for surgical removal. The Magseed Magnetic Marker is subsequently localized by using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (Endomag Sentimag® System, K153044 and K163541). The marker can be detected up to 3cm 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.

5.5 INTENDED USE

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

5.6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Endomagnetics has performed a comparison of the technological characteristics of the Magseed Magnetic Marker with those of the predicate device. Three differences in the technological characteristics (marker material, dimensions and surface finish) have been identified. Evaluation of the differences has determined that there are no new questions of safety or effectiveness.

5.7 DISCUSSION OF NON-CLINICAL TESTS SUBMITTED

Testing was conducted to evaluate and characterize the safety and performance of the Magseed Magnetic Marker. Pre-clinical testing included:

- Biological Evaluation
- Simulated Use

5.8 CONCLUSION

The Magseed Magnetic Marker has the same Intended Use as the predicate device. The different technological characteristics do not raise any new questions of safety or effectiveness. The test data presented in this submission demonstrate substantial equivalence of the Magseed Magnetic Marker with the predicate device.