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

March 2, 2016

Endomagnetics Ltd
Dr. Andrew Shawcross
Chief Operations Officer
The Jeffreys Building, Cowley Road
Cambridge, UK CB4 0WS

Re: K153044
Trade/Device Name: Sentimag System, Sentimark Magnetic Marker System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PBY
Dated: January 29, 2016
Received: February 1, 2016

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

4. INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Endomag Sentimark® Magnetic Marker

Indications for Use:

The Endomag Sentimark® Magnetic Marker is intended to be placed percutaneously in the breast to mark temporarily (< 30 days) a lumpectomy site intended for surgical removal. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (Endomag Sentimag® System) the Endomag Sentimark® Magnetic Marker is located and surgically removed with the target tissue.
The Endomag Sentimag® System is intended for the non-imaging detection and localization of the "Endomag Sentimark® Magnetic Marker" that has been implanted in a lumpectomy site intended for surgical removal.

Prescription Use __√____ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(K) SUMMARY

5.1 SUBMITTER INFORMATION

Submitter's Name:	Endomagnetics Ltd.
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	CB4 0WS
	United Kingdom
Contact Person:	Andrew Shawcross
	Chief Operations Officer
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Email:	ashawcross@endomag.com
Date summary prepared:	2nd March 2016

5.2 DEVICE INFORMATION

Trade name:	Sentimark Magnetic Marker and Sentimag System
Common name:	Tissue Marker, Marker Delivery System and Detection System
Classification name:	Implantable Clip
Regulation:	21 CFR 878.4300
Device Classification:	Class II
Product Code:	PBY

5.3 PREDICATE DEVICE

Cianna Medical Tissue Marker and Delivery System (K120804).

5.4 DESCRIPTION OF DEVICE

The Sentimag System is intended for the non-imaging detection and localization of the Sentimark Magnetic Marker that has been implanted in a lumpectomy site intended for surgical removal.

The Sentimag System and Sentimark Magnetic Marker System are 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 Sentimark Magnetic Marker 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 Sentimark 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.

5.5 INTENDED USE

The Endomag Sentimark® Magnetic Marker is intended to be placed percutaneously in the breast to mark temporarily (< 30 days) a lumpectomy site intended for surgical removal. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (Endomag Sentimag® System) the Endomag Sentimark® Magnetic Marker is located and surgically removed with the target tissue.
The Endomag Sentimag® System is intended for the non-imaging detection and localization of the "Endomag Sentimark® Magnetic Marker" that has been implanted in a lumpectomy site intended for surgical removal.

5.6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The K120804 predicate uses imaging technology to locate the device. This can be a handheld Ultrasound transducer. The Sentimark Magnetic Marker System utilizes non-imaging technologies that are comprised of a console that incorporates electronics and a simple user interface, plus a probe handpiece.

In both cases, a location marker is placed percutaneously in situ at the clinical target site by a delivery system. Both devices then employ the handpiece for the intraoperative detection and localization of the implanted marker.

In both systems 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.

The detailed technological characteristics of the two systems have been identified and compared. The minor differences in the technological characteristics do not raise any new questions of safety or effectiveness.

5.7 DISCUSSION OF NON-CLINICAL TESTS SUBMITTED

Performance testing was conducted to evaluate and characterize the performance of the Sentimag System and Sentimark Magnetic Marker System. Pre-clinical testing included:

- Dimensional Verification
- Insertion, Deployment and Withdrawal Force
- MRI Compatibility
- Simulated Use
- 28-Day GLP Implantation Trial

5.8 CONCLUSION

Endomagnetics believes that the Cianna Medical Tissue Marker and Delivery System (K120804) is the closest predicate device because it has the same intended use and very similar technological characteristics.

The Sentimag Magnetic Marker System 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, verification and validation data presented in this submission demonstrate substantial equivalence of the Sentimag Magnetic Marker System.