February 24, 2021

Sirius Medical Systems B.V.
Bram Schermers
Clinical Application Specialist
High Tech Campus 41
Eindhoven, North Brabant 5656AE
Netherlands

Re: K200734
Trade/Device Name: Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base Unit
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: PBY
Dated: January 18, 2021
Received: January 25, 2021

Dear Bram Schermers:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200734

Device Name

Sirius Pintuition Localization System (Sirius Pintuition Seed and Sirius Pintuition Detector)

Indications for Use *(Describe)*

The Sirius Pintuition Seed 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 (Sirius Pintuition Detector) the Sirius Pintuition Seed is located and surgically removed with the target tissue.

The Sirius Pintuition Detector is intended for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a lumpectomy site intended for surgical removal.

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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5 510(k) Summary

5.1 Submitter Information

Submitter's name: Sirius Medical Systems B.V.
Address: High Tech Campus 41
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Eindhoven
The Netherlands
Contact Person: Bram Schermers
Product Owner
Telephone: 0031 6 2011 6299
E-mail: bram.schermers@sirius-medical.com
Date summary prepared: March 9th, 2020

5.2 Device Information

Trade name: Sirius Pintuition Seed and Sirius Pintuition Detector
Common name / device: Temporary Tissue Marker
Regulation description: Implantable Clip
Regulation number: 21 CFR 878.4300
Regulatory Class: Class II
Review Panel: General & Plastic Surgery
Product Code: PBY

5.3 Predicate Device

Endomag Magseed and Sentimag (K163541)

5.4 Device Description

The Sirius Pintuition Seed and Sirius Pintuition Detector are part of the Sirius Pintuition Localization System.

The Sirius Pintuition Seed is a small (1.65 x 5mm) Titanium tissue marker that is intended to be placed percutaneously in the breast for temporary (<30 days) marking of a lumpectomy site intended for surgical removal. The device is supplied single-use, sterile and pre-loaded within its delivery needle (12cm or 20cm length).

The Pintuition Detector is designed to detect the presence and proximity of the implanted Pintuition Seed. It consists of a mains-powered, table-top Pintuition Base Unit, and a cable-connected, reusable Pintuition Probe. Using the Pintuition Probe, a user may use the Pintuition Detector prior to and during breast surgery to plan the surgical approach and guide surgery. The location of the seed is fed back to the user using audible and visual cues (distance in mm).

The principle of operation is magnetism, the Pintuition Seed is associated with a magnetic field which the Pintuition Detector utilizes to determine the location of the Pintuition Seed.

5.5 Intended Use

The Sirius Pintuition Seed 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 (Sirius Pintuition Detector) the Sirius Pintuition Seed is located and surgically removed with the target tissue.

The Sirius Pintuition Detector is intended for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a lumpectomy site intended for surgical removal.

5.6 Summary of Technological Characteristics

Elements of Comparison	Sirius Pintuition System	Predicate: Magseed Magnetic Marker System	Comparison
	SYSTEM		
510(k) ID	[TBD]	K163541	N/A
Regulation Number	§878.4300	§878.4300	Same
Regulation Description	Implantable Clip	Implantable Clip	Same
Regulatory Class	Class II	Class II	Same
Product Code	PBY	PBY	Same
Intended use	Temporary marking of a breast lumpectomy site for surgical removal	Temporary marking of a breast lumpectomy site for surgical removal	Same
Indications for use	The Sirius Pintuition Seed 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 (Sirius Pintuition Detector) the Sirius Pintuition Seed is located and surgically removed with the target tissue. The Sirius Pintuition Detector is intended for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a lumpectomy site intended for surgical removal.	The Endomag Magseed 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 Magseed 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 Magseed Magnetic Marker" that has been implanted in a lumpectomy site intended for surgical removal	Same
Type of Use	Prescription Use	Prescription Use	Same
Anatomical Locations	Breast	Breast	Same

Elements of Comparison	Sirius Pintuition System	Predicate: Magseed Magnetic Marker System	Comparison
Techno-logical Charac-teristics	The Sirius Pintuition System utilizes non-imaging technologies that are comprised of a console that incorporates electronics and a simple user interface, plus a probe handpiece. A location marker (Pintuition Seed) is placed percutaneously in situ 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. 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 Magseed 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. A location marker (Magseed) is placed percutaneously in situ 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. 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.	Same
DETECTOR			
Probe type	Handheld, flexible, cord-connected, reusable	Handheld, flexible, cord-connected, reusable	Same
Probe tissue contacting material	Poly Ether Ether Ketone (PEEK)	Poly Ether Ether Ketone (PEEK)	Same
User Feedback	Real-time visual and audible	Real-time visual and audible	Same
Sensing Depth	0-50 mm	0-30 mm	Similar. Sirius Pintuition System has improved sensing depth.
SEED/MARKER			
Seed/Marker Materials	Commercially Pure Titanium Grade II (Tissue-contacting) Neodymium magnet (Internal)	Surgical Grade Stainless Steel	Similar. Both biocompatible exterior. Internal material different due to different use of magnetism.
Seed/Marker diameter	1.65mm	1.0mm	Similar. Pintuition Seed is slightly larger to enable greater sensing depth.
Seed/Marker length	5.20mm	5.0mm	Similar
Sterility	Ethylene Oxide	Ethylene Oxide	Same
Visibility	X-ray, Ultrasound	X-ray, Ultrasound	Same
DELIVERY DEVICE			
Type	Preloaded, single-use, needle implanter	Preloaded, single-use, needle implanter	Same
Material	304 Stainless Steel	304 Stainless Steel	Same

Elements of Comparison	Sirius Pintuition System	Predicate: Magseed Magnetic Marker System	Comparison
Delivery device gauge	14G	18G	Similar. Pintuition gauge is slightly larger to enable implantation of larger Seed.

5.7 Summary of Non-Clinical Performance Data

Testing was conducted to evaluate and characterize the safety and performance of the Sirius Pintuition Localization System. Pre-clinical testing included:

- Design verification
- System accuracy and range verification
- Biocompatibility evaluation
- MR safety testing
- Sterilization validation
- Packaging validation
- Shelf life validation
- Electrical safety testing

5.8 Summary of Clinical Performance Data

An analysis of available data was conducted to evaluate and characterize the clinical safety and performance of the Sirius Pintuition Localization System. The clinical data support the safety and effectiveness of the device:

- Clinical Evaluation, including clinical safety and performance data with the actual device, a previous version of the device and an extensive evaluation of available literature data pertaining to the previous version device, the predicate device and additional benchmark devices.

5.9 Conclusion

The Sirius Pintuition Localization System has the same Intended Use as the predicate device. The different technological characteristics have not led to additional questions of safety or effectiveness. The data presented in the remainder of this submission show substantial equivalence of the Sirius Pintuition Localization System with the predicate device.