10/19/2022

Sirius Medical Systems B.V.
Bram Schermers
CEO/cto
High Tech Campus 41
Eindhoven, North Brabant 5656AE
Netherlands

Re: K222643
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: September 1, 2022
Received: September 1, 2022

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,

Deborah Fellhauer RN, BSN
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222643

Device Name
Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base Unit

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 inteded for surgical removal. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (Sirius Pintuition Detector) the Sirius Pintuition Seed can be 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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sirius medical	SPECIAL 510(K)		
	Meta	Identification: 002575	Version: 2.0
	Classification: PUBLIC		Page: 1 of 4
Title: K200734 Sirius Pintuition Probe Modification: Resterilization			

6 510(k) Summary

6.1 Submitter Information

Submitter's name: Sirius Medical Systems B.V.

Address: High Tech Campus 41
5656 AE
Eindhoven
The Netherlands

Contact Person: Bram Schermers
CEO

Telephone: 0031 6 2011 6299

E-mail: bram.schermers@sirius-medical.com

Date summary prepared: Monday, July 25, 2022

6.2 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

6.3 Predicate Device

Sirius Pintuition Seed and Sirius Pintuition Detector (K200734)

6.4 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 (7cm, 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.

6.5 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.

6.6 Summary of Technological Characteristics

Elements of Comparison	Sirius Pintuition System (Predicate)	Sirius Pintuition System (Changed)	Comparison
510(k) ID	K200734	[TBD]	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 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.	Same
Type of Use	Prescription Use	Prescription Use	Same
Anatomical Locations	Breast	Breast	Same

Elements of Comparison	Sirius Pintuition System (Predicate)	Sirius Pintuition System (Changed)	Comparison
Technological Characteristics	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 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.	Same
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
Probe sterility	Use of sterile sheath mandatory for use in sterile area	Use of sterile sheath no longer mandatory *if* sterilization is performed.	CHANGED
Reprocessing Instructions	Manual, wipe-based cleaning and disinfection	Manual, wipe-based cleaning and disinfection	Same
	Manual, immersion based high-level disinfection	Manual, immersion based high-level disinfection	Same
	No sterilization option provided.	Sterilization in STERRAD NX and NX100 systems	CHANGED
User Feedback	Real-time visual and audible	Real-time visual and audible	Same
Sensing Depth	0-50 mm	0-50 mm	Same
Seed/Marker Materials	Commercially Pure Titanium Grade II (Tissue-contacting) Neodymium magnet (Internal)	Commercially Pure Titanium Grade II (Tissue-contacting) Neodymium magnet (Internal)	Same
Seed/Marker diameter	1.65mm	1.65mm	Same
Seed/Marker length	5.20mm	5.20mm	Same
Sterility	Ethylene Oxide	Ethylene Oxide	Same
Visibility	X-ray, Ultrasound	X-ray, Ultrasound	Same
Type	Preloaded, single-use, needle implanter	Preloaded, single-use, needle implanter	Same
Material	304 Stainless Steel	304 Stainless Steel	Same
Delivery device gauge	14G	14G	Same

6.7 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:

- **ADDED**: Sterilization validation and functional compatibility testing.
- Design verification
- System accuracy and range verification
- Biocompatibility evaluation
- MR safety testing
- Sterilization validation
- Packaging validation
- Shelf life validation
- Electrical safety testing

6.8 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.

6.9 Conclusion

The Sirius Pintuition Localization System has the same Intended Use as the predicate device (K200734). The device is identical, apart from the changes proposed related to (re)sterilization of the Probe in STERRAD NX and NX100 systems. These changes do not impact substantial equivalence, the devices can be considered to be substantially equivalent.