November 9, 2023

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

Re: K223682
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: NEU
Dated: October 10, 2023
Received: October 10, 2023

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 (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,

Alexander Nguyen -S
2023.11.09 16:45:00 -05'00'

for Tek N. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223682

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 soft tissue to mark (>30 days) a biopsy site or a soft tissue 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 only for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a soft tissue biopsy site or a soft tissue 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1 510(k) Summary

1.1 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: Thursday, November 9, 2023

1.2 Device Information

Trade name: Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base Unit

Common name / device: Tissue Marker

Regulation description: Implantable Clip

Regulation number: 21 CFR 878.4300

Regulatory Class: Class II

Review Panel: General & Plastic Surgery

Product Code: NEU

1.3 Predicate and Reference Devices

510(k) Number	Trade Name	Submitter	Product Code	Primary Predicate (A)	Reference Device (B)
K222643	Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base Unit	Sirius Medical Systems	PBY	X	
K200734	Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base Unit	Sirius Medical Systems	PBY		X
K181007	Cianna Medical SAVI Scout Reflector and SAVI Scout System	Cianna Medical, Inc.	NEU		X

510(k) Number	Trade Name	Submitter	Product Code	Primary Predicate (A)	Reference Device (B)
K183400	EnVisio Navigation Sytem	Elucent Medical, Inc	NEU		X
K181692	5cm Tag Applicator, 7cm Tag Applicator, 10 Cm Tag Applicator, 5 Cm Tag Applicator (10 Pack), 7	Health Beacons, Inc.	NEU		X

1.4 Device Description

The Sirius Pintuition Seed and Sirius Pintuition Detector (consisting of Base Unit and Probe) are part of the Sirius Pintuition Localization System.

The Sirius Pintuition Seed is a small (1.65 x 5mm) Titanium tissue marker that is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures. The device is supplied single-use, sterile and pre-loaded within its delivery needle (7cm, 12cm or 20cm length variants).

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 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.

1.5 Intended Use

The Sirius Pintuition Seed is intended to be placed percutaneously in soft tissue to mark (>30 days) a biopsy site or a soft tissue 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 only for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

1.6 Summary of Technological Characteristics

Elements of Comparison	Sirius Pintuition System (Predicate, K222643)	Sirius Pintuition System (Modified)	Comparison
SYSTEM			
510(k) ID	K222643	K223682	N/A
Regulation Number	§878.4300	§878.4300	Same
Product Code Description	Implantable Clip	Marker, Radiographic, Implantable	MODIFIED[1]
Regulatory Class	Class II	Class II	Same
Product Code	PBY	NEU	MODIFIED[1]
Intended use	Temporary (<30 days) marking of a breast lumpectomy site intended for surgical removal	Long-term (>30 days) marking of a biopsy site or a soft tissue site intended for surgical removal	MODIFIED
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 soft tissue to mark (>30 days) a biopsy site or a soft tissue 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 only for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.	MODIFIED
Type of Use	Prescription Use	Prescription Use	Same
Anatomical Locations	Breast	Soft tissue	MODIFIED
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 (NO CHANGE)			
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	0-50 mm	Same
SEED (NO CHANGE)			

[1] PBY is the product code for 'Temporary Tissue Marker'. The current 510(k) is intended to extend the implantation duration for the Seed beyond what could be considered 'temporary', it is therefore more suited to be classified as "Marker, Radiographic, Implantable", which is code NEU, and matches the reference devices listed under 1p.3.

Elements of Comparison	Sirius Pintuition System (Predicate, K222643)	Sirius Pintuition System (Modified)	Comparison
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
DELIVERY DEVICE (NO CHANGE)			
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

1.7 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
- Compatibility analysis Pintuition Seed and implanted AIMDs

1.8 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 performance 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 in various soft tissue types.

1.9 Conclusion

The Sirius Pintuition Localization System has been compared to the legally marketed device (K222643) with respect to technological characteristics, performance, safety characteristics, labeling, and is similar in Intended Use. Non-clinical testing was conducted to verify and validate the performance of the device and ensure the Sirius Pintuition Localization System functions as intended and meets design specifications to perform the intended use. The device is identical to the predicate device, apart from the modification to the indications for use. These changes do not impact substantial equivalence, and the devices can be considered to be substantially equivalent.