December 20, 2024

Elucent Medical, Inc.
Judson Guericke
Vice President - Regulatory & Quality
6509 Flying Cloud Drive
Eden Prairie, Minnesota 55344

Re: K233639
Trade/Device Name: SmartClip Secure Soft Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: November 20, 2024
Received: November 20, 2024

Dear Judson Guericke:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Digitally signed by Alexander Nguyen -S
Date: 2024.12.20 13:17:02 -05'00'

for Tek N. Lamichhane, Ph. D.
Assistant Director
DHT4B: Division of 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)*
K233639

Device Name
SmartClip Secure Soft Tissue Marker

Indications for Use *(Describe)*
The implanted SmartClip® is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K233639

510(k) Summary

Prepared on: 2024-12-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Elucent Medical, Inc.
Applicant Address	6509 Flying Cloud Drive Eden Prairie MN 55344 United States
Applicant Contact Telephone	651-728-8855
Applicant Contact	Mr. Judson Guericke
Applicant Contact Email	judd.guericke@elucent.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SmartClip Secure Soft Tissue Marker
Common Name	Implanted, radiographic, tissue marker
Classification Name	Implantable clip
Regulation Number	878.4300
Product Code	NEU

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180640	SmartClip Soft Tissue Marker	NEU

Device Description Summary

21 CFR 807.92(a)(4)

The SmartClip® is an ethylene oxide sterile, single use device composed of a soft tissue marker preloaded in a delivery system. The marker is intended to be placed within soft tissue. The marker is visible using radiography (including mammographic imaging), ultrasound and MRI.

Marker:
A sterile, single use device permanently implanted marker is approximately 8 mm long and 1.25mm wide. The marker is placed into the barrel of the introducer and maintained prior to insertion by a biocompatible bone wax plug. The marker can be implanted into various types of soft tissue (e.g., lung, gastrointestinal system, and breast) and subsequently be detected by means of radiography (including mammographic imaging, ultrasound and MRI.

Delivery System:
The Delivery System consists of a stylet, a stylet-lock to prevent accidental deployment and 17ga introducer needle with male luer lock nut. The stainless steel needle is approximately 2.2 cm. The marker is preloaded inside the needle and retained by a bone wax plug. The male luer lock nut provides secure attachment to the proximal end of a biopsy needle. When the stylet is completely depressed the marker and bone wax plug are deployed from the end of the needle into the proximal end of the biopsy needle.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The implanted SmartClip® is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The SmartClip Secure Soft Tissue Marker (subject) and predicate SmartClip Soft Tissue marker differ in two primary ways. The SmartClip Secure Soft Tissue Marker has a PEEK retention feature that securely attaches to the glass vial component of the marker via a PET heat-shrink wrap. The predicate device does not have the PEEK retention feature or PET . Second, the delivery system of the subject and predicate device differs in one notable manner. The subject SmartClip Secure has a luer lock nut on the distal end which is meant to be fastened to a transbronchial access tool or a 17ga coaxial or introducer needle, whereas the predicate device has an introducer needle affixed to the hub portion of the of the delivery system.

The subject and predicate devices are identical in several aspects including the following:

Principle of Operation: The SmartClip marker(s) emit electromagnetic signatures which are then acquired and analyzed by the EnVisio System. These electromagnetic signatures are then translated into positional data visible to the physician.

Visualization Compatibility: SmartClip marker(s) are visible using radiography (including mammographic imaging), ultrasound, and MRI.

Implant Duration: The SmartClip marker(s) are permanently implantable devices.

Sterilization Method: The subject and predicate devices are sterilized by Ethylene Oxide to a sterility assurance level (SAL) of 10-6.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

All necessary testing has been performed for the SmartClip® Secure Soft Tissue Marker to assure substantial equivalence to the predicate device and demonstrate the device performs as intended.
The device design was qualified though the following tests:

- Simulated Use
- Mechanical Integrity
- Imaging Assessment
- MR Compatibility
- Biocompatibility (ISO 10993-1)
- Packaging (ISO 11607-1)
- Shelf Life
- Sterilization (ISO 11135)

Clinical testing is not applicable to support substantial equivalence.

SmartClip® Secure Soft Tissue Marker was verified to meet the all the product requirements and specifications. Tested units met the acceptance criteria as defined in formal verification protocols, meeting all functional requirements. Further, the fundamental scientific technology and indications for use have not changed. In conclusion, testing provided supports a determination that the subject device is substantially equivalent to the legally marketed predicated device.