June 4, 2018

Elucent Medical, Inc.
Ms. Debra Kridner
VP Regulatory and Quality
7480 Flying Cloud Drive, Suite 101
Eden Prairie, Minnesota 55344

Re: K180640
Trade/Device Name: SmartClip Soft Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 21, 2018
Received: May 22, 2018

Dear Ms. Kridner:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K180640

Device Name

SmartClip™ 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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) Summary

Following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92

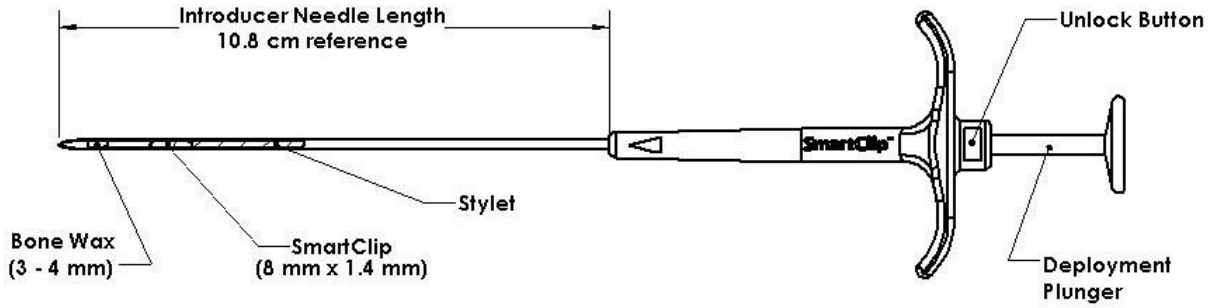
Date Prepared:	May 18, 2018
Applicant:	Elucent Medical, Inc. 7480 Flying Cloud Drive, Suite 110 Eden Prairie, MN 55344 | USA
Official Correspondent:	Debra Kridner Tel: (844) 417 1700 / Fax: (952) 314-7105 debra.kridner@elucent.com
Trade Name:	SmartClip™ Soft Tissue Marker
Common Name:	Implanted, Radiographic, Tissue Marker
Classification Number:	21 CFR 878.4300
Classification Name:	Implantable Clip
Device Class:	Class II
Product Code:	NEU
Review Panel:	General and Plastic Surgery
Predicate Device (primary):	Focal Therapeutics BioZorb Marker - K143484/K152070
Reference Device:	Cianna Medical Permanent Tissue Marker - K132463

Indications for Use for the Device Subject to this 510(k) Notification:

The 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.

Device Description for the Device Subject to this 510(k) Notification:

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.



SmartClip™

Marker:

A sterile, single use device permanently implanted marker is approximately 8 mm long and 1.4 mm wide. The marker is placed into the barrel of the introducer and maintained in place 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 15ga introducer needle. The stainless steel needle is approximately 10.8 cm long with 1cm depth reference marks. The marker is preloaded inside the needle and retained by a bone wax plug. When the stylet is completely depressed the marker and bone wax plug are deployed from the end of the needle.

Indications for Use Comparison:

Comparison of Subject Device to Predicate Device	**Subject Device (under review)**	**Primary Predicate Device** Focal Therapeutics BioZorb Marker (K143484/K152070)	**Reference Device:** Cianna Medical Permanent Tissue Marker (K132463)
Indications for Use	The 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.	The BioZorb LP Marker 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	The Cianna Medical Permanent Tissue Marker is intended to mark tissue during a percutaneous breast biopsy procedure and be permanently visible by radiography and visible for up to thirty days by ultrasound.
Intended Use	Implanted Soft Tissue Marker	Implanted Soft Tissue Marker	Implanted Soft Tissue – "Breast" Marker
Anatomical Site	Soft Tissue	Soft Tissue	Soft Tissue - Breast

Technological and Performance Characteristics Comparison:

Comparison of Subject Device to Predicate Device	**Subject Device (under review)**	**Primary Predicate Device** Focal Therapeutics BioZorb Marker (K143484/K152070)	**Predicate Device:** Cianna Medical Permanent Tissue Marker (K132463)
Overall Technological Characteristics	Radiographically visible permanent marker	Radiographically visible permanent marker	Radiographically visible permanent marker
Principle of Operation	Marker is positioned into tissue site for radiographic visualization of tissue site	Marker is positioned into tissue site for radiographic visualization of tissue site	Marker is positioned into tissue site for radiographic visualization of tissue site
Visualization Compatibility	X-Ray, Mammography Ultrasound, MR	X-Ray, Mammography Ultrasound, CT, MR	Radiographic and Ultrasound (30 days)
Deployment Method	Introducer	Manual, open surgical	Introducer
Implant Duration	Permanent	Permanent	Permanent
Marker Materials	Parylene C coated glass vial	Titanium (marker clip), bioabsorbable polymer (spacer)	Titanium beads and Nitinol
Sterility	Terminal sterilization by ethylene oxide, sterility assurance level 10^{-6}	Terminal sterilization by radiation, sterility assurance level 10^{-6}	Terminal sterilization by ethylene oxide, sterility assurance level 10^{-6}
Biocompatibility	Passed	Passed	Passed

Performance Testing:

All necessary testing has been performed for the SmartClip™ to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended.

The device design was qualified through the following tests:

- Simulated Use
- Mechanical Integrity
- Imaging Assessment
- MR Compatibility
- Biocompatibility
- Packaging
- Sterilization

Conclusion:

The SmartClip™ met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:

The Indications for Use, Intended Use, Fundamental Scientific Technology and Principles of Operation for the SmartClip™ are the same as those described for the predicate device. The SmartClip™ is found to have a safety and effectiveness profile that is the same as the predicate device and is determined by Elucent Medical to be substantially equivalent.

In summary, the SmartClip™ has the following similarities to the predicate device which have previously received 510(k) clearance:

- Has the same indications for use
- Has the same intended use
- Has the same implant duration
- Used in the same anatomical site
- Uses similar technological characteristics
- Uses the same principles of operation
- Uses biocompatible materials
- Has the same sterility assurance level

Therefore, the conclusions drawn from the nonclinical and clinical tests (biocompatibility) demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device predicate. The SmartClip™ is substantially equivalent to the predicate device.