March 22, 2019

Elucent Medical, Inc
Ms. Debra Kridner
Vice President of Regulatory and Quality
7480 Flying Cloud Drive, Suite 110
Eden Prairie, Minnesota 55344

Re: K183400
Trade/Device Name: EnVisio Navigation System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: February 20, 2019
Received: February 22, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Digitally signed by David Krause -S
Date: 2019.03.22 14:41:33 -04'00'

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)*
K183400

Device Name
EnVisio™ Navigation System

Indications for Use *(Describe)*
The SmartClip Soft Tissue Marker is intended to be placed percutaneously in soft tissue to permanently mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (EnVisio Navigation System); the SmartClip is located and surgically removed with the target tissue. The EnVisio Navigation System is intended only for the non-imaging detection and localization (by navigation) of the SmartClip 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.

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) Summary

Date Prepared: March 20, 2019

1. 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

2. DEVICE

Trade Name:	EnVisio™ Navigation System
510(k)	K183400
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

3. PREDICATE DEVICE (PRIMARY)

Trade Name:	Cianna Medical SAVI Scout Reflector and SAVI Scout System
510(k)	K181007
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

4. DEVICE DESCRIPTION (for the device subject to this 510(k) notification)

The EnVisio™ Navigation System is a medical device that detects the presence of the SmartClip™ Soft Tissue Marker(s) and provides real-time three-dimensional navigation during surgery. The EnVisio™ Navigation System acquires and analyzes electromagnetic signatures that display the relative distance, depth, and direction from the tip of the electrosurgical tool to the implanted SmartClips™ within the surgeon's field of view

during the procedure. The EnVisio™ Navigation System will be utilized in an operating room where surgical excision of soft tissue is performed. The EnVisio™ system can detect and provide real-time three-dimensional navigation for up to three separate SmartClips™ each programmed to emit a unique electromagnetic signature.

The EnVisio™ Navigation System equipment components are the Console, Heads Up Display, Patient Pad and Foot Pedal. The EnVisio™ Navigation System Navigator and Calibration Disk are sterile, non-patient contacting single use devices which are available separately.

5. INDICATIONS FOR USE (for the Device Subject to this 510(k) Notification)

The SmartClip™ Soft Tissue Marker is intended to be placed percutaneously in soft tissue to permanently mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (EnVisio™ Navigation System) the SmartClip™ is located and surgically removed with the target tissue. The EnVisio™ Navigation System is intended only for the non-imaging detection and localization (by navigation) of the SmartClip™ that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

Indications for Use Comparison:

Comparison of Subject Device to Predicate Device	Subject Device EnVisio™ Navigation System (K183400)	Predicate Device: Cianna Medical SAVI Scout Reflector and SAVI Scout System (K181007)
Indications for Use	The SmartClip™ Soft Tissue Marker is intended to be placed percutaneously in soft tissue to permanently mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (EnVisio™ Navigation System) the SmartClip™ is located and surgically removed with the target tissue. The EnVisio™ Navigation System is intended only for the non-imaging detection and localization (by navigation) of the SmartClip™ that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.	The SAVI Scout Reflector 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, MRI, or radiography) or aided by non-imaging guidance (SAVI Scout System) the SAVI Scout Reflector is located and surgically removed with the target tissue. The SAVI Scout System is intended only for the non-imaging detection and localization of the SAVI Scout Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.
Intended Use	Detect and Navigate to the implanted SmartClip - Soft Tissue Marker	Detect and Navigate to the implanted Reflector - Soft Tissue Marker
Use Environment	Intra-operative, guided surgical procedure	Intra-operative, guided surgical procedure
Anatomical Site	Soft Tissue	Soft Tissue
Patient Population	Adult	Adult

6. TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS COMPARISON

Comparison of Subject Device to Predicate Device	Subject Device EnVisio™ Navigation System (K183400)	Predicate Device: Cianna Medical SAVI Scout Reflector and SAVI Scout System (K181007)
Manufacturer	Elucent Medical, Inc.	Cianna Medical, Inc.
Device Name	EnVisio™ Navigation System	SAVI Scout Reflector and Scout System
510(k) Number	K183400	K181007
Principles of Operation	Electromagnetic wave technology to detect and navigate to the soft tissue marker	Electromagnetic wave technology to detect and navigate to the soft tissue marker
Intraoperative Localization Energy	Electromagnetic, passive marker	Electromagnetic, passive marker
Audible Location Indication	Yes	Yes
Visual Location Indication	Yes	Yes
Visualization Compatibility	Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (EnVisio Navigation System)	Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SAVI Scout System)
System Components (Equipment)	• Console • Heads-Up Display • Patient Pad • Foot Pedal (optional) • Cart	• Console
System Components (Sterile)	• Navigator • Calibration Disk	• Hand piece • Sterile Sheath applied to nonsterile Handpiece
Sterilization Method	Ethylene oxide	Ethylene oxide
Implanted Soft Tissue Marker	Yes - SmartClip	Yes - Reflector
Biocompatibility	Not applicable for Navigator and Calibration Disk – no direct or indirect patient contact	Yes -Handpiece has direct patient contact

Performance Testing:

Performance testing was conducted to evaluate and characterize the performance of the EnVisio Navigation System. The following performance testing was conducted on the EnVisio Navigation System to support a determination of substantial equivalence to the predicate device.

- System Design Verification
- Navigation Performance Verification
- Navigation Performance Validation

- EMC/Safety Testing
- Packaging/Shelf Life
- Sterilization Validation

Conclusion:

The EnVisio Navigation System 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 EnVisio Navigation System are the same as those described for the predicate device.

In summary, the EnVisio Navigation System has the following similarities to the predicate device which has previously received 510(k) clearance:

- Has substantially equivalent indications for use
- Has substantially equivalent intended use
- Used in substantially equivalent anatomical sites
- Uses substantially equivalent technological characteristics
- Uses substantially equivalent principles of operation
- Uses substantially equivalent sterilization methodology

Therefore, the conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device predicate. The EnVisio Navigation System is substantially equivalent to the predicate device.