November 10, 2020

Allotrope Medical Inc
% Allison Komiyama, Ph.D., R.A.C.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, CA 92110

Re: K200886
Trade/Device Name: StimSite
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: ETN
Dated: March 31, 2020
Received: April 2, 2020

Dear Allison Komiyama, Ph.D., R.A.C.:

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,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200886

Device Name
StimSite

Indications for Use *(Describe)*
StimSite is a non-sterile device intended to provide electrical stimulation to ureter smooth muscle tissue to help locate and identify ureters by testing ureter smooth muscle excitability.

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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510(k) Summary
K200886

DATE PREPARED
November 9, 2020

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DEVICE INFORMATION

Proprietary Name/Trade Name:	StimSite
Common Name:	Surgical Nerve Stimulator/Locator
Regulation Number:	21 CFR 874.1820
Class:	II
Product Code:	ETN
Review Panel:	Ear, Nose and Throat

PREDICATE DEVICE IDENTIFICATION
The StimSite is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K993436	UroMed CaverMap Surgical Aid / UroMed Corp.	✓
K092292	Checkpoint / NDI Medical LLC	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
StimSite is a non-sterile, non-patient contacting device that generates an electrical signal that elicits visible contractions of smooth muscle tissue. StimSite is a software-controlled signal box that is placed outside of the surgical field, and connects to standard, FDA cleared surgical instruments (sterile disposable, and reprocessed) that are designed to carry bipolar electrical signals through them such as laparoscopic Kleppingers, Maryland graspers and atraumatic graspers among others. StimSite is designed to provide the surgeon with the ability to generate a visible physiologic smooth muscle contraction response intraoperatively to identify and verify the ureter via characteristic muscle tissue movement. This device is intended for use as an adjunct to the standard of care visual assessment currently performed by surgeons to manually stimulate muscle tissue to identify ureters during surgical procedures.

StimSite is non-sterile, a piece of durable medical equipment that resides in the operating room. It is comprised of a Signal Box, a connected Footswitch with cable, and an Interconnect Cable. StimSite also utilizes a disposable Activation Card which tracks and manages device use, allowing a select number of procedures before it is exhausted and needs to be replaced. All materials of construction are common to use and comply with industry standards for use as durable medical equipment. Using the provided Interconnect Cable, surgeons have the option to connect to a currently marketed electrosurgical unit (ESU) or generator such as the Medtronic FT10, Conmed 2450, and the Megadyne Mega Power. StimSite is controlled by user selection buttons on the face of the device and a Footswitch is used to trigger a stimulation signal by the user. Through the selection buttons, StimSite can be placed in one of two modes: STIM (for stimulation) or ESU (for passthrough from the generator).

INDICATIONS FOR USE

StimSite is a non-sterile device intended to provide electrical stimulation to ureter smooth muscle tissue to help locate and identify ureters by testing ureter smooth muscle excitability.

COMPARISON TO PREDICATES

The subject device StimSite does not have the same indication for use as the predicates; however, the differences do not raise different safety or effectiveness questions. The subject and predicate devices have the same intended use to provide electrical stimulation to identify target tissues and test their excitability during surgery with delivery of signal into tissues done through a hand-held instrument.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

CHARACTERISTICS	**SUBJECT DEVICE StimSite**	**PREDICATE DEVICE UroMed CaverMap Surgical Aid**	**PREDICATE DEVICE Checkpoint 9041**
510(k) Number	**K200886**	**K993436**	**K092292**
Product Code / Regulatory Classification	**ETN/Class II** Surgical Nerve Stimulator/Locator 21 CFR § 874.1820	**ETN/Class II** Surgical Nerve Stimulator/Locator 21 CFR § 874.1820	**ETN/Class II** Surgical Nerve Stimulator/Locator 21 CFR § 874.1820
	Intended Use		
Intended Use	Intended to provide electrical stimulation to muscle tissue to locate and identify smooth muscle and test its excitability.	Intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.	Intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

CHARACTERISTICS	SUBJECT DEVICE StimSite	PREDICATE DEVICE UroMed CaverMap Surgical Aid	PREDICATE DEVICE Checkpoint 9041
	Technological Characteristics		
IEC 60601 Electrical Safety Standards Certification	Yes	Yes	Yes
Single-Use v. Re-Use	Re-Usable, Non-Disposable	Re-Usable, Non-Disposable	Single-Use
Device Configuration	Non-Disposable signal box that allows for connections to hand-held surgical instruments that deliver stimulation signal	Non-Disposable signal box that allows for connections to hand-held instruments that deliver stimulation signal	Hand-Held
Stimulus Tip	Metal bipolar-enabled surgical instruments designed to carry electrical signals to target tissues*	Metal bipolar-enabled instrument designed to carry electrical signals to target tissues	Metal ends designed to carry electrical signals to target tissues
Monopolar/Bipolar Stimulation	Bipolar stimulation signal (electrons flow from one tip to the other on the surgical instruments)	Bipolar stimulation signal (electrons flow from tip of instrument through the body to a clip applied to another surgical instrument)	Monopolar stimulation signal (electrons flow between blunt tip to needle tip)
Battery / AC Power	AC Powered	AC Powered	Battery Powered
Regulated Output	Fixed (single setting) output voltage	Fixed (single setting) output voltage, with adjustable current	Fixed (multi-setting) output current
Type of Waveform	Capacitor discharge waveform	Biphasic	capacitor discharge and square (biphasic waveform)
Stimulus Voltage and Current	40V peak 5.2V rms (maximum at 2500 ohm resistance) 5.9mA rms (maximum at 150 ohm resistance)	20mA maximum	30V maximum 20mA (maximum) 1.13mA rms (cathodic portion of waveform)
Stimulus Pulse Duration	250ms maximum pulse duration at 2500 ohm resistance	800us	200us maximum pulse duration up to 1500 ohm resistance

CHARACTERISTICS	SUBJECT DEVICE StimSite	PREDICATE DEVICE UroMed CaverMap Surgical Aid	PREDICATE DEVICE Checkpoint 9041
Stimulus Frequency	Single impulse delivery or maximum 1 Hz if foot pedal held down	16Hz	16Hz
Storage	In operating room or in surgical supply room	In operating room or in surgical supply room	In operating room or in surgical supply room
Compatibility with Surgical Generators	Connects with surgical generators to allow surgeons to still use their bipolar instruments in the traditional manner	Does not connect with any other surgical generators	Does not connect with any other surgical equipment

These differences in technological characteristics do not raise different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate substantial equivalence:

- Electrical Safety and EMC –StimSite complies with the following standards:
  - Safety and Essential Performance, per IEC 60601-1, Medical Electrical Equipment, Part 1: General Requirements
  - Safety and Essential Performance, per IEC 60601-2-2, Medical Electrical Equipment, Part 2-2: Particular Requirements of high frequency surgical equipment and accessories
  - Safety and Essential Performance, per IEC 60601-2-10, Medical Equipment, Part 2-10: Particular Requirements of nerve and muscle stimulators
  - Safety and Essential Performance, Per IEC 60601-1-2, Medical Electrical Equipment, Part 1-2, Collateral Standard: Electromagnetic disturbances
- Software Verification and Validation
  - Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.
- ESU Compatibility
- Temperature rise after StimSite Activation
- Animal Studies
  - GLP Animal Study "Evaluation of StimSite during laparoscopic surgery to locate retroperitoneal ureters without surgical dissection in a female Yorkshire pig model" for validating user acceptance and pathology to assure use without tissue injury. Three representative device users (2 Ob/Gyn surgeons and 1 General and Trauma Surgeon) conducted a simulated exploratory surgery in which they were instructed to identify the

ureters using traditional methods followed by StimSite activation. StimSite was connected to an ESU and also evaluated for successful bipolar cautery performance. Users were able to identify the ureters in all cases with StimSite. No use errors were noted and users concluded that the device meets user needs. A laparotomy was then performed on the other side of the animal and a StimSite stimulation was delivered to tissue in one location and in another the grasper was used to grasp tissue but no stimulation was provided. There was no evidence of thermal injury or trauma to any specimen.

- Human Factors testing, per ISO 62366-1 Medical devices – Part 1: Application of usability engineering to medical device
  - Initial testing included 5 intended users. Participants were provided with the Instructions for Use (IFU) to review and then were observed for performance of tasks and any use errors or problem in an animal model. No issues were noted.
  - Subsequent testing included 19 surgeons (14 general and 5 Ob/Gyn surgeons) with varying levels of clinical experience and training. The participants reviewed the IFU, Summary Use Card, and participated in an in-service training session. The general/colorectal surgeons performed a laparoscopy with peritoneal biopsy near the ureter and the Ob/Gyn surgeons performed a laparoscopic hysterectomy in a live porcine model in an operating room with support staff after a 1 hour break. Observational data was collected via direct observation. Knowledge task data was obtained from participants following completion of the review of the IFU, Summary Use Card and in-service training. All surgeons were able to successfully perform their surgical procedures. There were two errors noted in which the surgeons allowed the instrument tips to touch. There is no potential harm associated with this error and the users were able to self-correct. There was some feedback provided on the error tone length which led to an increase in the tone duration for the StimSite.

SUMMARY OF CLINICAL TESTING

Between September 11, 2018 and December 3, 2019, 11 total procedures were performed where StimSite was used during the operation. All procedures were gynecologic procedures with 2 being robotic gynecologic operations, 8 being handheld laparoscopic instrument operations and 1 case being an open abdominal procedure. These procedures included hysterectomies (open, laparoscopic and robotic), endometriosis ablation/resections (laparoscopic), and fibroid ablation/resections (laparoscopic). These procedures were carried out by 2 Ob/Gyns with 10 procedures carried out by one surgeon and 1 by the other surgeon.

Through this first in human clinical pilot, the StimSite smooth muscle stimulation technology was determined to be safe to use, specific for and efficacious in eliciting a visible ureter muscular contraction during surgery. Across a range of different procedures and instruments including handheld bipolar instruments and robotic bipolar instruments, the StimSite signal was delivered appropriately as long as the 3rd party instrument was itself assembled correctly. Surgeon feedback through the questionnaire confirmed clinical utility of the technology.

CONCLUSION

The testing performed, including software testing, electromagnetic compatibility testing, electrical safety testing, bench performance testing, animal testing, human factors testing and clinical evaluation, support a substantial equivalence determination.