November 18, 2020

Viveve Medical, Inc.
Kevin Robison
Regulatory Affairs Specialist
345 Inverness Drive South, Building B, Suite 250
Englewood, Colorado 80112

Re: K200472
Trade/Device Name: Viveve System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 22, 2020
Received: October 23, 2020

Dear Kevin Robison:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200472

Device Name
Viveve System

Indications for Use *(Describe)*
The Viveve System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.

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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510(k) SUMMARY

1.1 REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

1.2 APPLICANT INFORMATION

Applicant: Viveve® Inc.
345 Inverness Drive South
Building B, Suite 250
Englewood, CO 80112

Contact: Kevin Robison
krobison@viveve.com
C: 317-435-8898
F: 720-696-8199

Date Prepared: November 18, 2020

1.3 SUBJECT DEVICE INFORMATION

Trade Name: Viveve® System
Common Name: Electrosurgical System
Product Code: GEI
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Device Panel: General Surgery/Restorative Device
Device Classification: Class II

1.4 PREDICATE DEVICES

Primary Predicate Device: Viveve® System (K180584)
Reference Device: Viveve® 2.0 System (K190422)

1.5 DEVICE DESCRIPTION

The Viveve System utilizes monopolar radiofrequency (RF) energy to selectively heat a given volume of tissue beneath the surface, while cryogen is delivered to the inside of the treatment tip to cool the surface tissue. The generator delivers energy to the treatment tip to create an electric field under the treatment tip (electrode). The mechanism of action is the application of RF energy to the tissue resulting in coagulation and/or hemostasis.

The Viveve® System consists of four (4) primary components:

- An RF Generator to provide the heating energy. The Generator incorporates the Cooling Module to supply coolant which provides the cooling energy.
- A hand piece that couples the cooling and heating energy to the tissue through the treatment tip.
- A footswitch that allows the user to turn the RF Energy on or off.
- 5cm or 8cm Sterile Disposable Treatment Tips.

The Viveve treatment tips contained in this package are a sterile single use component of the Viveve® System and designed to deliver radiofrequency (RF) energy from the Viveve console. The Viveve treatment tips can only be used in conjunction with the dedicated Viveve® System.

Accessories include:

- Coupling Fluid
- Cryogen
- Return Cable
- Return Pad
- Power Cord

1.6 INDICATIONS FOR USE

The Viveve System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.

1.7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the subject device Viveve System are identical to those of the predicate devices, Viveve System (K180584) and Viveve 2.0 System (K190422). The Viveve System is an electrosurgical device that delivers radiofrequency (RF) energy to selectively heat a given area of tissue, while cryogen is delivered to the inside of the treatment tip to cool the surface tissue at the end of energy deposition. The application of RF energy causes the tissue to coagulate and/or become hemostatic.

This submission application confirms the continued conformance to applicable technical design specifications and performance requirements, including requirements associated with industry safety and performance standards.

1.8 BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Viveve System is substantially equivalent to the predicate devices listed in K180584 and K190422. The principle of operation between the predicate devices and the subject device remain identical as do all output parameters to tissue.

1.8.1 DESIGN MODIFICATIONS

1.8.1.1 RF Console (Generator)

- No changes have been made to the Console.

1.8.1.2 Footswitch

- No changes have been made to the Footswitch.

1.8.1.3 Handpiece

- No changes have been made to the Handpiece.

1.8.1.4 Cryogen

- No changes have been made to the Cryogen.

1.8.1.5 Treatment Tip

- The packaging of the sterile Treatment Tip has changed to align with the packaging of the secondary predicate Viveve 2.0 System (K190422) packaging.

1.8.2 SOFTWARE MODIFICATIONS

1.8.2.1 Viveve RF Console Software

- No changes have been made to the RF Console Software.

1.8.2.2 Viveve RF Display Module Software

- No changes have been made to the RF Display Module Software.

1.8.2.3 Viveve RF Handpiece Software

- The handpiece software has been changed since the previous clearance (K180584). The handpiece software has been slightly modified to extend the useful life of the handpiece from 11,000 radiofrequency emitting pulses to a minimum of 65,000 radiofrequency pulses. The change in pulse number was validated and assessed for additional risk to the patient and was deemed non-significant. The change was made to allow the customer to use the handpiece for more treatments improving customer satisfaction and lowering operational costs. Further detail on this change can be found in the Viveve Letter to File dated December 5th, 2019 and is available upon request.

1.8.3 HARDWARE MODIFICATIONS

1.8.3.1 Operating System

- No changes have been made to the Operating System.

1.8.4 LABELING MODIFICATIONS

1.8.4.1 Technical User Manual

- No changes have been made to the TUM for the Viveve System.

1.8.4.2 Instructions for Use

- No changes have been made to the IFU for the Viveve System.

1.8.5 TECHNICAL/ENVIRONMENTAL SPECIFICATION MODIFICATIONS

1.8.5.1 Environmental and Packaging Specifications

- IEC60601, Electrostatic Discharge (ESD) and Voltage Dip are aligned with CMO's Quality Management System (QMS) Requirements

1.8.5.2 RF Frequency

- No changes have been made to the RF Frequency output.

1.8.5.3 Operation temperature

No changes have been made to the Operation Temperature.

1.8.5.4 Storage pressure

- No changes have been made to the Storage Pressure.

1.8.6 CONTRACT MANUFACTURER AND CONTRACT STERILIZER MODIFICATIONS

- Cirtec Medical will now be the sole contract manufacturer of the Viveve System sterile Treatment Tip replacing Stellartech Research Corporation (SRC) upon clearance of this submission.
- STERIS will be the Contract Sterilizer for the Viveve System sterile Treatment Tips upon clearance of this submission.

All previously outlined modifications to the Viveve System are discussed in further detailed in **Section 12: Substantial Equivalence Discussion** of this Premarket Notification. A comparison of the technical characteristics of Viveve System are compared to those of the predicate device, Viveve System, in **Table 1-1** below.

Table 1-1: Comparison of Technological Characteristics of Viveve System and Cleared Primary Predicate Viveve System (K180584)

Item	Viveve System (Subject Device)	Viveve System (Primary Predicate Device K180584)
510(k) Number	Subject device	K180584
Legal Manufacturer	Viveve, Inc.	Viveve, Inc.
Contract Manufacturer	• Stellartech Medical Systems (Generator and Handpiece) • **Cirtec Medical (Treatment Tips)**	• Stellartech Research Corporation (All 3 system components)
Indication for Use	The Viveve System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.	The Viveve System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.
FDA Classification	Class II	Class II
CFR/Product Code	21 CFR 878.4400/GEI	21 CFR 878.4400/GEI
Invasiveness of Treatment	Non-invasive. Device applies to the surface.	Non-invasive. Device applies to the surface.
Principles of Operation	Radiofrequency (RF) energy selectively heats a given volume of tissue beneath the surface, while cryogen is delivered to the inside of the Treatment Tip to cool the surface tissue.	Radiofrequency (RF) energy selectively heats a given volume of tissue beneath the surface, while cryogen is delivered to the inside of the Treatment Tip to cool the surface tissue. The Treatment Tip is placed on the

Item	Viveve System (Subject Device)	Viveve System (Primary Predicate Device K180584)
	The Treatment Tip is placed on the surface of the skin and the internal tissues are heated while the surface tissue is protected. (Reverse thermal gradient)	surface of the skin and the internal tissues are heated while the surface tissue is protected. (Reverse thermal gradient)
Energy	RF	RF
Treatment Type	Monopolar	Monopolar
Main Input (Input voltage/Current/Frequency)	100 - 120 Vac / 10A / 50/60 Hz 220 - 240 Vac / 5A / 50/60 Hz	100 - 120 Vac / 10A / 50/60 Hz 220 - 240 Vac / 5A / 50/60 Hz
Maximum Power (generator)	240 Watts	240 Watts
Operating Frequency	6 MHz ±2%.	6 MHz ±2%.
Voltage Waveform	6.0 MHz continuous sinusoidal waveforms	6.0 MHz continuous sinusoidal waveforms
Electrode Probe	Monopolar	Monopolar
Impedance Range	25 – 120 Ω	25 – 120 Ω
Tip	5cm and 8cm Treatment Tips	5cm and 8cm Treatment Tips
Packaging	Tyvek pouch	Tyvek pouch
Sterility	ETO	ETO
Contract Sterilizer	STERIS	Sterigenics
Cooling Solution	Cryogen	Cryogen

1.9 BIOCOMPATIBILITY

The biocompatibility endpoints for limited contact duration were conducted on the Viveve System sterile Treatment Tip.

1.10 PERFORMANCE DATA

Design verification testing, including bench performance, electrical safety/electromagnetic compatibility, software verification/validation, packaging and shelf-life studies, provided in the subject premarket notification demonstrate that the Viveve System is substantially equivalent to the predicate device, Viveve System.

1.10.1 Performance Data

Design development and control is conducted in phases as described in the Cirtec Design and Development Plan PLN-200054 and VIDA-L Quality Plan QP-200027. The Core Team is responsible for executing and adhering to this VIDA-L Design and Development Plan, and for compliance to Cirtec's

Quality Management System, unless otherwise stated in the Plan. The Core Team consists of representatives from Cirtec and Viveve.

The following document describes the Design Control of the Viveve System Treatment Tips by Cirtec Medical.

Document Title	Document Number
Design Control Procedure	Cirtec QSP-C110004

1.11 CONCLUSION

The design, technical characteristics, functionality, indications for use, and principle operation of the subject device Viveve System remains unchanged from that of the predicate device, Viveve System (K180584) and reference devicefor K190422. The proposed treatment tip manufacturer and sterilization facility modifications do not raise new questions of the safety or efficacy of the device and the intended use of the Viveve System remains unchanged from that of the cleared predicates.