January 16, 2020

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

Re: K193611
Trade/Device Name: Viveve 2.0 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 23, 2019
Received: December 26, 2019

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, PhD
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)*
K193611

Device Name
Viveve 2.0 System

Indications for Use *(Describe)*
The Viveve 2.0 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.

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SECTION 5

510(k) SUMMARY

5.1 REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

5.2 APPLICANT INFORMATION

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

Contact: Kevin Robison
Regulatory Affairs Specialist
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F: 720-696-8199

Date Prepared: December 23, 2019

5.3 SUBJECT DEVICE INFORMATION

Trade Name: Viveve® 2.0 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

5.4 PREDICATE DEVICE

Viveve 2.0 System (K190422)

5.5 DEVICE DESCRIPTION

The Viveve 2.0 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 causing coagulation and/or hemostasis.

The Viveve® 2.0 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.

Accessories include:

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

5.6 INDICATIONS FOR USE

The Viveve 2.0 System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.

5.7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the subject device Viveve 2.0 System are substantially equivalent to the predicate device, Viveve 2.0 System (K190422). The Viveve 2.0 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. The subject device differs from the predicate device in the addition of Contact Quality Monitoring (CQM). The device software monitors the return pad to determine if it is adequately secured to the patient's body in order to dissipate any residual radiofrequency energy. The display module software differs from that of the predicate device only in the addition of a Contact Map which indicates the amount of contact between the return pad and the patient's skin. In all other regards the display module software is identical. The design specifications of the subject device are identical to the predicate device specifications with the sole exception of the addition of CQM and the modification to the user interface.

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

5.8 BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Viveve 2.0 System is substantially equivalent to the predicate device listed in K190422. The principle of operation between the predicate device and the subject device remain the same as do all output parameters to tissue.

Specifications of the Viveve 2.0 System are discussed in further detailed in **Section 09: Substantial Equivalence Discussion** of this Premarket Notification. A comparison of the technical characteristics of Viveve 2.0 System are compared to those of the predicate device, Viveve 2.0 System, in **Table 5-1** below.

Table 5-1: Comparison of Technological Characteristics of Subject Viveve 2.0 System and previously cleared Viveve 2.0 System (K190422)

Item	Viveve 2.0 System (Subject Device)	Viveve 2.0 System (Predicate Device K190422)
510(k) Number	Subject device	K190422
Legal Manufacturer	Viveve, Inc.	Viveve, Inc.
Contract Manufacturer	• Sparton Medical Systems Colorado, LLC • Cirtec Medical (Treatment Tips)	• Sparton Medical Systems Colorado, LLC • Cirtec Medical (Treatment Tips)
Indication for Use	The Viveve 2.0 System is indicated for use in general surgical procedures for electrocoagulation and hemostasis.	The Viveve 2.0 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. 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)	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 surface of the skin and the internal tissues are heated while the surface tissue is protected. (Reverse thermal gradient)
Energy	RF	RF
Contact Quality Monitoring	Yes	No
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)	50 Watts	50 Watts
Operating Frequency	6.78 MHz ±15%.	6.78 MHz ±15%.
Voltage Waveform	6.78 MHz continuous sinusoidal waveforms	6.78 MHz continuous sinusoidal waveforms
Electrode Probe	Monopolar	Monopolar

Item	Viveve 2.0 System (Subject Device)	Viveve 2.0 System (Predicate Device K190422)
Impedance Range	20 – 185 Ω	20 – 185 Ω
Tip	5cm and 8cm Treatment Tips	5cm and 8cm Treatment Tips
Packaging	Tyvek pouch	Tyvek pouch
Sterility	ETO	ETO
Cooling Solution	Cryogen	Cryogen

5.9 PERFORMANCE DATA

Verification testing, including electrical safety/electromagnetic compatibility, software verification/validation were performed for the addition of the Contact Quality Monitoring software and the revised display module software to the Viveve 2.0 System.

1. Sparton Medical performed software and hardware verifications to ensure the Contact Quality Monitoring worked appropriately. The following verifications were performed as part of the Sparton Medical Hardware Verification Test Report 140154:
    - The RF Generator was tested to ensure CQM contact resistance was working appropriately. The contact resistance measurement range was 0 to 200 Ω with ±10% (100 Ω – 200 Ω range) and ± 10 Ω accuracy (< 100 Ω).
    - The RF Generator shall have a CQM circuit response time constant of <20 ms.).
    - The RFG hardware shall support detection and provide means to disable the RF output for the following operating condition error: Loss of patient contact.

2. Intertek performed the following IEC and EMC testing on the Viveve 2.0 System with CQM added:
    - Constructional Data Report according to:
        - Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005 + C1;A2}
        - Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (R2013) {CSA C22.2#60601-1:2008 Ed.2 + C2]
        - Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety and Essential Performance – Collateral Standard: Usability [IEC 60601-1-1-6:2010 Ed.3+A1]
        - Medical Electrical Equipment – Part 2-2: Particular Requirements For The Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories [IEC 60601-2-2:2017 Ed.6]
    - EMC Test Report according to:
        - IEC 60601-1-2 ed. 4.0 (2014-02): Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances –

Requirements and tests (With EMC deviations per IEC 60601-2-2:2017:03)

- Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance according to:
  - IEC 60601-1:2005, OR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
- Medical Electrical Equipment Part 1-6: General Requirements for Safety – Collateral Standard: Usability according to:
  - IEC 60601-1-6:2010, AMD1:1013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, OR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)
- Medical Electrical Equipment Part 2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories according to:
  - IEC 60601-2-2: 2017 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR 2:2007, AMD1:2012 or IEC 60601-1:2012

All the above Intertek test reports are on file at Viveve and are available in full upon request.

3. Viveve performed a master Viveve 2.0 System Validation to ensure the CQM software performs appropriately. The following parameters were tested:
   - Ensure the CONTACT MAP graphic within the Graphic User Interface is not illuminated when the Return Pad is not connected to the phantom tissue (pork belly) and is illuminated green when the Return Pad is connected to the phantom tissue.
   - When the Return Pad is not adequately connected to the phantom tissue, the RF Generator will fault and result in an E63 – Check Tip Contact error. Acknowledge the error by selecting OK. Place the Return Pad securely on the phantom tissue so that the CONTACT MAP is illuminated and ensure a pulse is delivered.

The Verifications, EMC and IEC Testing, and Validation ensure that the CQM addition to the Viveve 2.0 System are performing to the correct specifications for safety and efficacy of the device.

5.10 CONCLUSION

The following results were achieved referencing the tests performed in 1-3 above:

1. The RF Generator performed as expected when the contact resistance was measured at the appropriate values. The CQM reading was as expected between 50 Ω ± 10 Ω with the RF Activated. The voltage on channel 1 of the oscilloscope transitioned 63% of the way from low too high in <= 20ms. The RF Generator did fault when the CQM circuit was not complete resulting in radiofrequency interruption to the patient. **All of the above parameters were met and were recorded as PASS results.**
2. Intertek performed the above tests according to the applicable standards. **All of the above parameters were met and were recorded as PASS results.**

3. During the execution of the protocol, all tested functions performed as expected. Test results indicated that the CQM updates to the Viveve 2.0 System have met the impacted customer requirements, identified within ENG-017 Impact Analysis for CQM Updates.
   The Viveve 2.0 System successfully passed all functional testing performed in the protocol.

Noting all testing performed above, considering the risk and safety of the device, the Viveve 2.0 System performed as expected after the addition of the CQM Software. The changes to the Viveve 2.0 System Software do not raise questions of safety or efficacy of the overall system; therefore, the Viveve 2.0 System is substantially equivalent to the predicate device.