September 14, 2021

Viveve Medical, Inc.
Kevin Robison
Global Manager, Regulatory Affairs
345 Inverness Drive South, Building B, Suite 250
Englewood, Colorado 80109

Re: K212678
Trade/Device Name: Viveve System, 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: August 23, 2021
Received: August 24, 2021

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)*
K212678

Device Name
Viveve System and Viveve 2.0 System

Indications for Use *(Describe)*
The Viveve System and Viveve 2.0 System are 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. REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

2. APPLICANT INFORMATION

Applicant: Viveve Inc.
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Building B, Suite 250
Englewood, CO 80112

Contact: Kevin Robison
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C: 317-435-8898
F: 720-696-8199

Date Prepared: August 23, 2021

3. SUBJECT DEVICE INFORMATION

Trade Name: Viveve® System and 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

4. PREDICATE DEVICE

Viveve System (K200472) and Viveve 2.0 System (K193611)

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® System and Viveve® 2.0 System consist 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

The return pad is the subject of this submission. Previously, Viveve specified and supplied the user with the 3M model 9160 electrosurgical return pad. Viveve is seeking to add additional return pad options for the user with the following characteristics:

- United States FDA clearance
- A split pad with no cord attached.
- Conducted area is between 40 cm^2 and 120 cm^2.
- Measured impedance between 20-140 ohms.

Viveve has performed testing on three similar return pads. The testing revealed that the pads with the above specifications perform equivalent to each other when used with both the Viveve System and Viveve 2.0 System.

The reason for this change is because the 3M model 9160 electrosurgical return pad is currently unavailable worldwide. Also of note is that Viveve supplies the return pad for its users. Only tested and approved return pads with the above specifications will be distributed for treatment.

6. INDICATIONS FOR USE

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

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the subject devices Viveve System and Viveve 2.0 System are identical to the predicate devices, Viveve System (K200472) and Viveve 2.0 System (K193611). The Viveve System and Viveve 2.0 System are electrosurgical devices that deliver radiofrequency (RF) energy to selectively heat a given area of tissue. In contrast, 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.

The Viveve System and Viveve 2.0 System are identical to the systems cleared in K193611 and K200472, respectively. The systems may now use different Viveve supplied models of return pads, provided the pads meet the following specifications:

- United States FDA clearance
- A split pad with no cord attached.
- Conducted area is between 40 cm^2 and 120 cm^2.
- Measured impedance between 20-140 ohms.

8. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Viveve System and Viveve 2.0 System are substantially equivalent to the predicate device listed in K200472 and K193611. The principle of operation between the predicate device and the subject device remains the same as do all output parameters to tissue.

8.1 DESIGN SPECIFICATIONS

8.1.1 RF Console (Generator)

- Overall footprint of the RF Console and corresponding case (weight, shape and size) is identical to the predicate device.

8.1.2 Footswitch

- The footswitch is identical to the predicate device.

8.1.3 Handpiece

- The handpiece is identical to the predicate device.

8.1.4 Cryogen

- R134a (1,1,1,2 tetrafluoroethane) or 1234ze (trans 1,3,3,3-Tetrafluoroprop-1-ene) is the Cryogen used with the Viveve 2.0 System.

8.1.5 Treatment Tip

- The Contract Manufacturing Organization of the Viveve 2.0 System Treatment Tips is Cirtec Medical.
- The Contract Sterilizer remains STERIS Isomedix Services.
- Treatment Tip packaging remains identical to the cleared device.

8.1.6 Return Pad

- The return pad is a xxcm2 grounding pad that is utilized for the safe return of electrosurgical energy from the patient's body back to the electrosurgical unit. A return pad is required for the same and effective use of the Viveve System and Viveve 2.0 Systems.
- **Viveve is seeking the addition of any return pad with the specifications listed in Section 5.5 instead of specifying the 3M model 9160 return pad.**

8.2 SOFTWARE SPECIFICATIONS

8.2.1 Viveve RF Console Software

- The software in the console is identical to the predicate devices.

8.2.2 Viveve RF Display Module Software

- The software in the display module is identical to the predicate devices.

8.2.3 Viveve RF Handpiece Software

- The software in the handpiece is identical to the predicate devices.

8.3 HARDWARE

8.3.1 Operating System

- The operating system is identical to the predicate devices.

8.4 LABELING MODIFICATIONS

8.4.1 Technical User's Manual

- The Technical User's Manual (TUM) for both systems will be updated to include the specifications listed in **Section 5.5** instead of specifying the user to use the 3M model 9160 return pad. REDLINE and FINAL versions of the TUM are included as part of this submission.

8.4.2 Instructions for Use

- The Instructions for Use are identical to the predicate devices.

8.5 TECHNICAL/ENVIRONMENTAL SPECIFICATIONS

8.5.1 Environmental and Packaging Specifications

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

8.5.2 RF Frequency

- Remains identical to the predicate devices.

8.5.3 Operation temperature

- The operational temperature remains identical to the predicate devices.

8.5.4 Storage pressure

- Range is aligned with that outlined in packaging and environmental testing.

8.6 CONTRACT MANUFACTURER ORGANIZATIONS (CMO)

- Spartronics is the contract manufacturer of the display and handpiece for the Viveve 2.0 System.

- The Viveve System display and handpiece were manufactured by Stellartech Research Corporation. (The Viveve System is no longer in active production, though many systems are still being utilized for treatments.)

- Cirtec Medical remains the manufacturer of the 5cm and 8cm Treatment Tips.

- STERIS Isomedix Services remains the contract sterilizer of the Treatment Tips.

Specifications of the Viveve System and Viveve 2.0 Systems are discussed in further detailed in **Section 7: Comparison of Technological Characteristics with the Predicate Device** of this Premarket Notification.

9. PERFORMANCE DATA

Design verification testing, including electrical safety/electromagnetic compatibility, software verification/validation have been performed on both the Viveve System and Viveve 2.0 System.

10. CONCLUSION

The design, technical characteristics, functionality, indications for use, and principle operation of the subject device Viveve 2.0 System remains unchanged from that of the predicate devices, Viveve System (K200472) and Viveve 2.0 System (K193611).

The addition of compatible return pads do not raise questions of safety or efficacy of the overall system; therefore, the Viveve System and Viveve 2.0 System are substantially equivalent to the predicate devices.