February 2, 2022

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

Re: K213814
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 6, 2021
Received: December 7, 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)*
K213814

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.

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
Global Manager, Regulatory Affairs
krobison@viveve.com
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F: 720-696-8199

Date Prepared: December 6, 2021

1.3 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

1.4 PREDICATE DEVICE

Viveve® 2.0 System (K212678)

1.5 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

1.6 INDICATIONS FOR USE

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

1.7 BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Viveve 2.0 System is substantially equivalent to the predicate device listed in K212678. The manufacturing site is changing from Sparton Medical in Frederick, CO to Spartronics in Watertown, SD. No changes to the console, handpiece or any other components are being made. No changes to software or indications for use are being updated as part of the manufacturing site change. Also, no changes to the device specifications or labeling are being made.

1.7.1 COMPARISON OF TECHNOLOGY CHARACTERISTICS AND SE DETERMINATION

1.7.1.1 RF Console (Generator)

- The Console is not changing as part of this submission.

1.7.1.2 Footswitch

- The Footswitch is not changing as part of this submission.

1.7.1.3 Handpiece

- The Handpiece is not changing as part of this submission.

1.7.1.4 Cryogen

- Cryogen has not changed as part of this submission.

1.7.2 SOFTWARE MODIFICATIONS

1.7.2.1 Viveve RF Console Software

- Console Software is not changing as part of this submission.

1.7.2.2 Viveve RF Display Module Software

- Display Module software is not changing as part of this submission.

1.7.2.3 Viveve RF Handpiece Software

- Handpiece software is not changing as part of this submission.

1.7.3 HARDWARE MODIFICATIONS

1.7.3.1 Operating System

- The Operating System is not changing as part of this submission.

1.7.4 LABELING MODIFICATIONS

1.7.4.1 Technical User Manual

- No changes have been made to the Technical User Manual.

1.7.4.2 Instructions for Use

- No changes have been made to the Instructions for Use.

1.7.5 TECHNICAL/ENVIRONMENTAL SPECIFICATION MODIFICATIONS

1.7.5.1 Environmental and Packaging Specifications

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

1.7.6 CONTRACT MANUFACTURER MODIFICATIONS (CMO)

- **Spartronics in Watertown, SD is now the manufacturing and servicing provider for the Viveve 2.0 System.**

1.8 PERFORMANCE DATA

Design verification testing, including bench performance and software verification/validation, provided in the subject premarket notification demonstrate that the Viveve 2.0 System is substantially equivalent to the predicate device, Viveve 2.0 System.

1.9 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 device, Viveve 2.0 System (K212678). The proposed contract manufacturer modifications do not raise new questions of the safety or efficacy of the device and the intended use of the Viveve 2.0 System remains unchanged from that of the cleared predicate.