April 6, 2018

Viveve Inc.
Suzon Lommel
Senior Vice President, Regulatory & Quality Affairs
345 Inverness Drive South, Building B, Suite 250
Englewood, Colorado 80112

Re: K180584
Trade/Device Name: Viveve RF System, Secure
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 19, 2018
Received: March 5, 2018

Dear Suzon Lommel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

K180584

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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SECTION 7

510(k) SUMMARY

7.1 REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

7.2 APPLICANT INFORMATION

Applicant:	Viveve Inc. 345 Inverness Drive South B-250 Englewood, CO 80112
Contact:	Suzon Lommel Senior VP, Quality Assurance and Regulatory Affairs slommel@viveve.com Phone: (408) 645-4979 Fax: (720) 696-8199
Date Prepared:	February 19, 2018

7.3 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 Devices
Device Classification:	Class II

7.4 PREDICATE DEVICE

- Viveve System (K162547)

7.5 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 causing 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 the coolant which provides the cooling energy.
- A hand piece that couples the cooling and heating energy to the tissue through the treatment tip (below).
- A footswitch that allows the user to turn the RF Energy on or off.
- 5 cm and 8cm Sterile Disposable Treatment Tips.

Accessories include:

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

7.6 INDICATION FOR USE

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

7.7 TECHNICAL CHARACTERISTICS

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.

7.8 SUBSTANTIAL EQUIVALANCE

The Viveve System is substantially equivalent to the predicate device listed. The principle of operation between the predicate device and the subject device remain the same, however the subject device is modified with a design change to add an8 cm Treatment Tip. These changes have been tested and verified to have no effect on system functionality, safety, or effectivity. The function of the subject device, the materials and indication for use have not changed, therefore, the subject device is substantially equivalent to the predicate device listed.

Table 7.8.1: Summary Comparison of Technical Characteristics

Item	Viveve System and Accessories (Subject Device)	Viveve System (Predicate Device)
510(k) Number	Subject 510(k)	K162547
Legal Manufacturer	Viveve, Inc.	Viveve, Inc.
Contract Manufacturer	Stellartech Research Corporation	Stellartech Research Corporation

Item	Viveve System and Accessories (Subject Device)	Viveve System (Predicate Device)
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 applied to the surface.	Non-invasive. Device applied to the surface.
Principles of operations	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
Treatment Type	Monopolar	Monopolar
Input power	100-240 VAC @ 50/60 Hz	100-240 VAC @ 50/60 Hz
Maximum power (generator)	240 Watts	240 Watts
Operating Frequency	6 MHz	6 MHz
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	5 cm and 8cm Treatment Tips	5 cm Treatment tip
Packaging	Tyvek Pouch	Tyvek Pouch
Sterility	ETO	ETO
Cooling solution	Cryogen	Cryogen

7.9 PERFORMANCE DATA

The modifications made to the Viveve System were found to not affect safety or performance through design verification bench testing, which confirmed the continued conformance to applicable technical design specifications and performance requirements, including requirements associated with industry safety and performance standards, as follows:

- Safety and essential performance testing in accordance with IEC 60601-1:2005 (2006/07-3rd edition) and IEC 60601-2-2:2009

- Electromagnetic compatibility in accordance with IEC 60601-1-2:2007
- Design verification testing to ensure the proposed modifications perform within design parameters under the proper environmental conditions.
- Software validation was conducted to ensure the proposed modification perform with the design parameters.

7.9.1 Non-Clinical Performance Data

Design verification and biocompatibility testing was performed to ensure the subject device Viveve System functions according to the intended use. The results met the acceptance criteria. Risk analysis was also completed in accordance with criteria based on ISO 14972:2007. Electromagnetic compatibility and electrical safety testing was completed in compliance with IEC 60601-1 and IEC 60601-1-2. Biocompatibility testing was conducted for the Treatment Tip and Coupling Fluid according to ISO 10993-1:2009. Other components of the Viveve System do not have direct contact with patient tissue, therefore biocompatibility testing was not required. Sterilization for the subject device remains the same as the predicate device sterilization method and parameters. Packaging validation testing was also completed against the subject device along with the shelf life testing.

7.9.2 Clinical Performance Data

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence as the only change was to the length of the Treatment Tip shell, all internal components are identical.

7.10 CONCLUSION

The indications for use and the technical characteristics of the Viveve System has not changed from the predicate device. The results of performance testing demonstrate that the modifications to the Viveve System do not affect the safety, efficacy, or performance of the System, therefore, the subject device is substantially equivalent to the predicate device.