DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 3, 2015

DePuy Mitek Incorporated
Ms. Susan Kagan
Project Manager
325 Paramount Drive
Raynham, Massachusetts 02067

Re: K143475
Trade/Device Name: VAPR® Tripolar 90™ Suction Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 5, 2015
Received: March 6, 2015

Dear Ms. Kagan:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143475

Device Name
VAPR® Tripolar90™ Suction Electrode

Indications for Use *(Describe)*

The VAPR Electrodes, for use with the VAPR VUE Radiofrequency System, are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DePuy Synthes
MITEK SPORTS MEDICINE
COMPANIES OF Johnson & Johnson

510(k) SUMMARY

I. SUBMITTER

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Susan Kagan
Project Manager, Regulatory Affairs

Date Prepared: December 4, 2014

II. DEVICE

Name of Device:	VAPR® TRIPOLAR 90™ Suction Electrode
Common/Usual Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories: 21 CFR 878.4400
FDA Classification:	II
FDA product code:	GEI

III. PREDICATE

Primary Predicate: CoolPulse 90 Electrode-K113545/ K100638
Reference Device: ArthroCare Super Turbovac-K120791

These predicate devices have not been the subject of a design related recall.

IV. DEVICE DESCRIPTION

The VAPR TRIPOLAR 90 Suction Electrode is a single use, one-piece bipolar RF suction electrode for use in a surgical setting by a surgeon trained in arthroscopic surgery.

The VAPR TRIPOLAR 90 Suction Electrode is an RF device which incorporates 3 electrodes in the probe tip: one active electrode and two return electrodes. This configuration optimizes ablation and coagulation in a single device.

It has been designed to facilitate access and control the delivery of RF energy to the joint space. The connector plug of the VAPR TRIPOLAR 90 Suction Electrode is designed to interface only with the VAPR VUE Radiofrequency Generator. It has an internal identification code which automatically adjusts the VAPR VUE Generator to the optimal default and accessible powers and waveforms. If required, the settings for the VAPR TRIPOLAR 90 Suction Electrode can be modified within safe pre-determined limits by accessing the generator or footswitch control. It is intended to be only operated with the VAPR VUE generator at pre-determined default settings specific for this device.

The VAPR TRIPOLAR 90 Suction Electrode has three sets of buttons to address surgeon preference when holding the electrode. Each pair of buttons offers the same functionality and are ergonomically positioned for surgeon comfort.

In addition the VAPR TRIPOLAR 90 Suction Electrode features vacuum fluid extraction which enhances the efficiency of the electrode and assists in the removal of bubbles and debris created during activation within the operating site. The design includes the ability to vary flow rate to allow the surgeon to make adjustments depending on particular procedural requirements.

V. INDICATION FOR USE

The VAPR Electrodes, for use with the VAPR VUE Radiofrequency System, are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

The Indication for Use statement for the VAPR TRIPOLAR 90 Suction Electrode is not identical to the predicate devices however both the subject device and the predicates devices are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVICE

Component	VAPR CoolPulse90 Electrode	VAPR TRIPOLAR 90 Suction Electrode
FDA Clearance	Predicate Device K100638/K113545	Subject Device
Indication for Use	The VAPR Electrodes for use with the VAPR VUE Radiofrequency System are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow, and wrist.	The VAPR Electrodes, for use with the VAPR VUE Radiofrequency System, are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.
Working Length	160mm	155mm
Tip Geometry	oval tip w/suction slot & partial peripheral suction	near oval tip w/suction & partial peripheral suction
Integrated Cable and Plug	Yes	Yes
Integrated Hand Control	Yes	Yes
Integrated Suction	Yes	Yes
RF Energy	Bipolar	Bipolar
Sterilization	Gamma Irradiation	Gamma Irradiation

VII. PERFORMANCE DATA

Biocompatibility

The biocompatibility evaluation of the VAPR TRIPOLAR 90 Suction Electrode was conducted in accordance with FDA Blue Book Memorandum # G95-1 "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing," May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity

The VAPR TRIPOLAR 90 Suction Electrode is considered an external communicating device used for a duration of less than 24 hours.

Electrical safety

Electrical Safety was conducted on the VAPR TRIPOLAR 90 Suction Electrode when used with the VAPR VUE generator. The system complies with IEC 60601-1 “Medical electrical equipment -- Part 1: General requirements for safety and IEC 60601-2-2 “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”

Software Status

The VAPR TRIPOLAR 90 Suction Electrode is compatible only with the VAPR VUE generator. The generator was previously programed to recognize the VAPR TRIPOLAR 90 Suction Electrode so no software update was required.

Performance Data

The following performance data were provided in support off the substantial equivalence determination.

TEST	RESULTS
• Tissue Tests	Acceptable
• Saline Outflow Temperature Test	Acceptable
• Fingerswitching Tests	Acceptable
• Suction Control	Acceptable
• Area of Thermal Margin	Acceptable
• Clogging Frequency	Acceptable
• Active Tip Compression	Acceptable
• Active Tip Side Load	Acceptable
• Three Point Bend Test	Acceptable
• Fluid Ingress	Acceptable
• System Compatibility	Acceptable
• Thermal Shock	Acceptable
• In-joint Temperature Test	Acceptable
• Surface Contact Temperature Test	Acceptable

Animal Study

No animal studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The VAPR TRIPOLAR 90 Suction Electrode does not differ from the predicate device in fundamental scientific technology or intended use.

Clinical Study

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The VAPR TRIPOLAR 90 Suction Electrode does not differ from the predicate device in fundamental scientific technology or intended use.

VIII. CONCLUSION

Results of performance and safety testing have demonstrated that the modified device is suitable for its intended use.

Based on the indications for use, fundamental scientific technology, and comparison to the predicate devices, the VAPR TRIPOLAR 90 Suction Electrode is shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.