K082643

DEC 19 2008

510(k) Summary

VAPR Electrodes (end effect, side effect, wedge, angled, hook, flex, side effect short and wedge short), VAPR TC Electrode and VAPR Suction Electrodes (S^{90} and S^{50}) with Integrated Handpiece

Submitter's Name and Address:	DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767, USA	
Contact Person	Zheng Liu Regulatory Affairs Specialist DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-977-3966 Facsimile: 508-977-6955 e-mail: zliu8@its.jnj.com	
Name of Medical Device	Classification Name:	Electrosurgical cutting and coagulating device and accessories
	Common/Usual Name:	Electrosurgical System and Electrodes
	Proprietary Name:	VAPR S^{90} Electrode
		VAPR 3.5 mm Side effect Electrode with Integrated Handpiece
		VAPR 3.5 mm Hook Electrode with Integrated Handpiece
		VAPR 3.5 mm Angled Side Effect Electrode with Integrated Handpiece
		VAPR 2.3 mm Wedge Electrode with Integrated Handpiece
		VAPR 2.3 mm Wedge Electrode (Short) with Integrated Handpiece
		VAPR S^{50} Electrode

	VAPR 3.5 mm Flex Side Effect Electrode with Integrated Handpiece VAPR 2.3 Side Effect Electrode (Short) with Integrated Handpiece, 85 mm VAPR 2.3 End Effect Electrode with Integrated Handpiece, 140 mm VAPR Temperature Control (TC) End Effect Electrode with Integrated Handpiece, 2.3 mm x 140 mm
Substantial Equivalence	The **VAPR S^{90} Electrode** is substantially equivalent to the VAPR LPS (Low Profile Suction) Electrode (K041135, 05/10/2004). The **VAPR 3.5 mm Side effect Electrode with Integrated Handpiece** is substantially equivalent to the Side Effect Electrode (K963783, 09/19/1996 & K974022, 01/12/1998). The **VAPR 3.5 mm Hook Electrode with Integrated Handpiece** is substantially equivalent to the 90° Hook Electrode (K963783, 09/19/1996 & K974022, 01/12/1998). The **VAPR 3.5 mm Angled Side Effect Electrode with Integrated Handpiece** is substantially equivalent to the Angled Side Effect Electrode (K963783, 09/19/1996 & K974022, 01/12/1998). The **VAPR 2.3 mm Wedge Electrode with Integrated Handpiece** is substantially equivalent to the 2.3mm Wedge Electrode (K000936, 04/19/2000). The **VAPR 2.3 mm Wedge Electrode (Short) with Integrated Handpiece** is substantially equivalent to the 2.3mm Wedge Electrode Short (K000936, 04/19/2000). The **VAPR S^{50} Electrode** is substantially equivalent to the VAPR LPS (Low Profile Suction) Electrode (K041135, 05/10/2004). The **VAPR 3.5 mm Flex Side Effect Electrode with Integrated Handpiece** is substantially equivalent to the Flex Side Effect Electrode (K963783, 09/19/1996 & K974022, 01/12/1998). The **VAPR 2.3 Side Effect Electrode (Short) with Integrated Handpiece, 85 mm** is substantially equivalent to the 2.3 VAPR Side Effect Electrode (Short) (K992876, 09/24/1999). The **VAPR 2.3 End Effect Electrode with Integrated Handpiece, 140 mm** is substantially equivalent to the 2.3 VAPR End Effect

	Electrode (K992406, 08/06/1999). The **VAPR Temperature Control (TC) End Effect Electrode with Integrated Handpiece, 2.3 mm x 140 mm** is the VAPR TC Electrode (K002402, 08/31/2000).
Device Classification	Electrosurgical cutting and coagulating device and accessories have been classified as Class II, GEI (21 CFR 878.4400).
Device Description	The device description of the **VAPR 3.5 mm and 2.3 mm Electrodes (end effect, side effect, wedge, angled, hook, flex, side effect short and wedge short) with Integrated Handpiece** is as follows. The DePuy Mitek VAPR System is designed for arthroscopic surgical procedures. The System consists of a high frequency Electrosurgical Generator, disposable Electrodes with integrated Handpiece, and a Footswitch. The components are designed and intended to be operated as a single unit. The device description of the **VAPR TC Electrode with Integrated Handpiece** is as follows. The VAPR Temperature Control Electrode is a soft tissue desiccation device intended for use with the VAPR Systems. Utilization with a VAPR System allows the tip temperature of the electrode to be indicated on the generator display. The device description of the **VAPR Suction Electrodes (S^{90} and S^{50})** is as follows. The VAPR Suction Electrodes are soft tissue ablation and desiccation devices intended for use with the VAPR System. They extend the utility of the system by removing bubbles created during activation from the operating site.
Indications for Use	The **VAPR Electrodes (end effect, side effect, wedge, angled, hook, flex, side effect short and wedge short) and VAPR Suction Electrodes (S^{90} and S^{50}) with Integrated Handpiece** with Integrated Handpiece, when used with the DePuy Mitek VAPR Electrosurgical System, are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist. The **VAPR TC Electrode with Integrated Handpiece**, when used with the DePuy Mitek VAPR Electrosurgical System, is intended for coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, and wrist.

Safety and Performance	In support of the 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's subcontractor Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification. Based on the Indications for Use, technological characteristics and safety and performance testing, the **VAPR Electrodes (end effect, side effect, wedge, angled, hook, flex, side effect short and wedge short), VAPR TC Electrode and VAPR Suction Electrodes (S^{90} and S^{50}) with Integrated Handpiece** have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Depuy Mitek
% Ms. Zheng Liu
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

DEC 19 2008

Re: K082643
Trade/Device Name: VAPR Electrodes with Integrated Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 24, 2008
Received: November 26, 2008

Dear Ms. Liu:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: VAPR Electrodes with Integrated Handpiece

Indications For Use:

The **VAPR Electrodes (end effect, side effect, wedge, angled, hook, flex, side effect short and wedge short) and VAPR Suction Electrodes (S^{90} and S^{50}) with Integrated Handpiece** with Integrated Handpiece, when used with the DePuy Mitek VAPR Electrosurgical System, are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.

The **VAPR TC Electrode with Integrated Handpiece**, when used with the DePuy Mitek VAPR Electrosurgical System, is intended for coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, and wrist.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082643