DePuy Mitek Inc. never stop moving

K100638

# 510(k) SUMMARY

JUN 18 2010

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| ***Date Prepared*** | March 4, 2010 |
| ***Submitter's Name and Address:*** | DePuy Mitek, Inc.<br>*a Johnson & Johnson company*<br>325 Paramount Drive<br>Raynham, MA 02767 |
| ***Contact Person*** | Susan Kagan<br>Project Manager, Regulatory Affairs<br>DePuy Mitek, Inc.<br>*a Johnson & Johnson company*<br>325 Paramount Drive<br>Raynham, MA 02767, USA<br>Telephone: 508-880-8097<br>Facsimile: 508-977-6955<br>e-mail: skagan@its.jnj.com |
| ***Name of Medical Device*** | Classification Name: Electrosurgical cutting and coagulation device and accessories: 21 CFR 878.4400<br><br>Common/Usual Name: Electrosurgical cutting and coagulation device and accessories: Arthroscope<br><br>Proprietary Name: VAPR® VUE™ Radiofrequency System<br>P50 Electrode<br>P90 Electrode<br>CP90 Electrode<br>CP90 Electrode with Handcontrol<br><br>FDA Classification: II<br><br>FDA product code: GEI |
| ***Predicate Device(s)*** | The proposed **VAPR VUE Radiofrequency System** is substantially equivalent to:<br>▪ K041135: VAPRIII™ (May 10, 2004)<br><br>The proposed **VAPR VUE Radiofrequency System** is also similar to:<br>▪ K031085: Gyrus SuperPulse Electrosurgical Generator (July 21, 2003) |

The proposed Wireless Footswitch is substantially equivalent to:

- K083161: ConMed Linvatc Zen Wireless Footswitch
- K053510: Linemaster IR Wireless Footswitch System
- K033135: Stryker Wireless Universal Footswitch

The proposed **P90 and CP90 Electrodes** are substantially equivalent to:

- K002422: VAPR 90° Suction Electrode (August 31, 2000)
- K041135: VAPR LPS Electrode (May 10, 2004)
- K082643: VAPR Electrodes with Handpieces (December 19, 2008)

The proposed **P50 Electrode** is substantially equivalent to:

- K992876: The 2.3 Wedge Effect Electrode ( September 24, 1999)
- K041135: VAPR LPS Electrode (May 10, 2004)
- K082643: VAPR Electrodes with Handpieces (December 19, 2008)

***Device Description***

The **VAPR VUE Radiofrequency System** is DePuy Mitek's next generation of VAPR Radiofrequency Systems. The system consists of a generator, wired or wireless footswitch and electrodes. The VAPR VUE generator was designed to provide comparable RF performance with legacy VAPR electrodes.

As with its predicate devices including the VAPR 3 generator, this electrosurgical system utilizes bipolar technology specifically designed to provide a range of arthroscopic surgical treatments including soft tissue ablation, contouring, cutting and coagulation and temperature control.

The VAPR VUE system offers five output types of operation: Vaporization (ablation), Coagulation, CP Vaporization (ablation), Blended Vaporization (ablation and coagulation) and temperature control coagulation. All types are present in the predicate device (VAPR3 generator) except the CP Vaporization (ablation).

The **VAPR P50** and **P90** Electrodes are an addition to the family of LPS Electrodes. These Suction Electrodes are soft tissue ablation and coagulation devices intended for use with the VAPR Electrosurgical Systems. They extend the utility of the system by removing bubbles created during activation from the operating site.

The **VAPR CP90** Electrodes are identical in technological characteristics as the P90 electrode only it is intended to be run only off the VAPR VUE platform at pre-determined default settings specific for the device. The CP90 with Handcontrols offers the integration of handcontrol capabilities via three buttons molded on the existing one-piece handles. These

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| | buttons control ablation, coagulation and the generator mode functions. |
| ***Indications for Use*** | The Mitek VAPR VUE Radiofrequency System is intended for resection, ablation and excision of soft tissue, and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.<br><br>The P50 and P90 Electrodes when used with Mitek VAPR Electrosurgical Systems are intended for resection, ablation and excision of soft tissue, and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.<br><br>The VAPR CP90 Electrodes when used with Mitek VAPR VUE Electrosurgical System is intended for resection, ablation and excision of soft tissue, and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist. |
| ***Comparison to Predicate Device*** | This submission is intended to demonstrate that the VAPR VUE Radiofrequency System, P50, P90 and CP90 Electrodes are substantially equivalent to their legally marketed devices.<br><br>The Electrodes have been carefully compared to legally marketed devices with respect to intended use, essential components and material, performance specifications and technology characteristics. All of the electrodes which are the subject of this submission have the same Indications for Use and technology characteristics. Changes include:<br><br>• The P50 electrode is identical to its predicate with the exception of default power which falls within the generator specification.<br><br>• P90 and CP90 active tip and suction electrode material change.<br><br>• The CP90 Electrodes is provided with non- handcontrol version as well a handcontrol capability which uses the same fundamental technology as the wired footswitch.<br><br>The VAPR VUE Radiofrequency System has been compared to legally marketed devices with respect to intended use, performance and technology characteristic. The VAPR VUE has the same Indications for Use and technology characteristics.<br><br>• Enhancements on the VAPR VUE generator include: |

- CP output type
- Open the range of Peak power output

In addition safety and performance testing have been done to validate the performance and safety of the device. It has been demonstrated that these device modifications will not affect safety and effectiveness of the subject devices.

***Safety and Performance***

Verification of the VAPR VUE System and Electrodes includes electrical, software and performance tests to show that the device meets its product specifications over a range of operating conditions. Validation testing for the VAPR VUE includes testing to show the device meets user needs. Verification testing conform to the following Standards and Guidance documents:

**TABLE 1 Standards & Guidance Documents**

| Standard/Guidance | Description |
|---|---|
| EN 60601-1: 1995 | Medical electrical equipment -- Part 1: General requirements for safety |
| EN60601-2-2:2007 | Medical electrical equipment -- Part 2-2: Particular requirements for the safety of high frequency surgical equipment |
| EN60601-1-2: 2006 | Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. |
| EN 60601-1-4/A1:2005 | EN 60601-1-4/A1 2005 electrical equipment - Part 1-4: general rules of security - Collateral Standard: electrical systems programmable |
| ISO 60601-1-4 | Medical Electrical Equipment: Part 1-4 General requirements for collateral standard: Programmable electrical medical systems. |
| ISO 62304 | Medical device software-software life cycle process |
| Guidance for the Content of Premarket Submission for Software Contained in Medical Devices: 2005 | |
| General Principals of Software Validation; Final Guidance for Industry and FDA Staff: 2002 | |
| Guidance Off-The-Shelf Software Use in Medical Devices: 1999 | |

***Clinical Testing***

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The VAPR

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| | VUE Radiofrequency System and Electrodes do not differ from the predicate device in fundamental scientific technology or intended use. |
| ***Conclusion*** | Results of performance and safety testing have demonstrated that the modified device is suitable for its intended use.<br><br>Based on the indications for use, fundamental scientific technology, and comparison to the predicate devices, the VAPR VUE Radiofrequency System, along with the Premiere50, Premiere90 and CP90 Electrodes are shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Depuy Mitek, A Johnson & Johnson Company
% Ms. Susan Kagan
Project Manger, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K100638
Trade/Device Name: VAPR Electrodes
VAPR VUE Radiofrequency System including wireless footswitch and electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 15, 2010
Received: June 17, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: **VAPR Electrodes**

Indications for Use:

The DePuy Mitek VAPR Electrodes for use with all VAPR Electrosurgical Systems 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, ankle, elbow, and wrist.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100638

# Indications for Use

510(k) Number (if known):

Device Name: **VAPR VUE Radiofrequency System including Wireless Footswitch and Electrodes**

Indications for Use:

The Mitek VAPR VUE Radiofrequency System is intended for resection, ablation and 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 DePuy Mitek 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, ankle, elbow, and wrist.

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

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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