



JAN 12 1998

ETHICON, INC.  
a Johnson & Johnson company

60 GLACIER DRIVE • WESTWOOD • MA • 02090  
PHONE (781) 251-2700 • TOLL-FREE (800) 356-4835 • FAX (781) 461-9166

K974022

## SUMMARY OF SAFETY AND EFFECTIVENESS

DATE November 7, 1997

### 510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

DEVICE NAME Mitek Vapr™ System  
CLASSIFICATION NAME Arthroscope and Accessories (21CFR 888.1100)  
TRADE NAME/PROPRIETARY NAME Vapr™

PREDICATE DEVICE NAME  
Oratec Interventions™ Model ORA 50 Electrothermal Generator and Accessories.

### SUMMARY

#### Device Indications:

The Mitek Vapr™ Generator and Accessories, in combination with Vapr thermal / coagulating probes (electrodes), is designed for general surgical use, including orthopaedic and arthroscopic applications of resection, ablation, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues.

#### Technological Characteristics:

The Mitek Vapr system is technologically the same as the predicate device. Both devices use high frequency electrosurgical current to achieve the intended clinical purpose. The predicate device is mono-polar and the Mitek device is bi-polar. This difference does not raise any new question of safety and effectiveness.

#### Device Description:

The Mitek Vapr™ system is comprised of four components: the electrosurgical generator, a footswitch, a handpiece with a cable to connect to the generator and five types of electrode tip configurations used in the arthroscopic procedure.

**PERFORMANCE DATA**

Preclinical animal studies and laboratory evaluations were conducted to show that the device functions as intended. In preclinical laboratory evaluations, the Oratec system was used for comparison. Clinical data was deemed unnecessary to support the Premarket Notification. Sufficient data has been obtained from preclinical animal testing to assess safety and effectiveness characteristics of the device when compared to the predicate device.

**CONCLUSIONS**

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

**CONTACT**

Mr. Edward F. Kent  
Vice President  
Regulatory Affairs / QA  
Mitek Products  
60 Glacier Drive  
Westwood, MA 02090



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Edward F. Kent  
Vice President, Regulatory Affairs  
Mitek Products  
60 Glacier Drive  
Westwood, Massachusetts 02090

JAN 12 1998

Re: K974022  
Trade Name: VAPR™  
Regulatory Class: II  
Product Code: GEI  
Dated: October 10, 1997  
Received: October 14, 1997

Dear Mr. Kent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

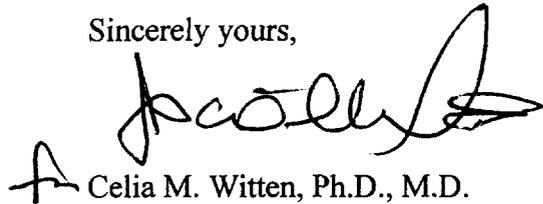
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K974022

510(k) Number (if known): \_\_\_\_\_

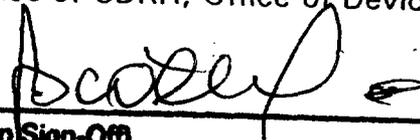
Device Name: Mitek Vapr System

Indications For Use:

The Mitek Vapr Generator and Accessories, in combination with Vapr thermal / coagulating probes (electrodes), is designed for general surgical use, including orthopaedic and arthroscopic applications of resection, ablation, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues.

(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 General Restorative Devices

510(k) Number K974022

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

