K992529

NOV 1 7 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:
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Name of the Device: Tissue Spectroscope

- **Predicate Devices:** The Tissue Spectroscope is substantially equivalent to a combination of the Laserflow BPM^2, the INVOS 3100A Cerebral Oximeter and the LKB-Wallac 1230 Arcus Fluorometer.

Description of the Device: The Tissue Spectroscope is a device that carries out various in-vivo, spectroscopic measurements. It is a combination device consisting of an NADH Fluorometer and a Laser Doppler Flowmeter. The Tissue Spectroscope is used to transmit radiation at a known wavelength through tissue and to measure the fluorescence of NADH and the intensity of light reflected from the tissue, including the Doppler shift arising from the moving red blood cells.

The Tissue Spectroscope measures the following three parameters:

1. Mitochondrial NADH fluorescence at 420 nm to 480 nm.
2. Doppler shifted laser light (325nm) reflected from moving blood cells.
3. Total backscattered light (325nm) reflected from the tissue. This parameter allows for correction of the NADH fluorescence measurement due to changes in tissue blood volume.

These three parameters contain information, respectively, pertaining to the redox state of mitochondrial NAD/NADH of the tissue, microvascular blood flow in the tissue and total blood volume of the tissue. Changes in these values reflect changes in the balance between oxygen supply and oxygen demand.

The differences between the systems raise no new issues of safety or effectiveness.

July 25.99
Date

A. Mayevsky
Prof. Avraham Mayevsky, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2000

VITAL Medical Ltd.
c/o Bruce F. Mackler, Ph.D.
Heller Ehrman White & McAuliffe
815 Connnecticut Ave N.W.
Suite 200
Washington, D.C. 20006-4004

Re: K992529
Trade Name: Tissue Spectroscope
Regulatory Class: II (two)
Product Code: DPW, DQA, KHO
Dated: August 29, 2000
Received: August 29, 2000

Dear Dr. Mackler:

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 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). 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 (Premarket 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) 594-4648. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K992529

Device Name The Tissue Spectroscope

Indications For Use:

The Tissue Spectroscope is indicated for in-vivo monitoring of changes in NADH redox state and microvascular perfusion in tissue. Changes in these parameters provide information on tissue metabolic activity.

(for Miriam Provost

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

11-15-00

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992529

Prescription Use_____ OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)