K031556

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510(k) Summary

General Information

Classification	Class II
Trade Name	VivaTherm™ Temperature Measurement System
Submitter	Vivant Medical, Inc. 1916-A Old Middlefield Way Mountain View, CA 94043 650-694-2900
Contact	Steven Kim Vice President, Research & Development

Intended Use

The VivaTherm™ Temperature Measurement System is intended to monitor tissue temperatures during clinical procedures requiring temperature feedback.

Predicate Devices

Luxtron Multichannel 2000 Fluoroptic Thermometer	K841105
Endocare Electronic Thermometer System	K961365
URI Therm-X Model TX-100 Multichannel Thermocouple Thermometry System	K843381

Device Description

The VivaTherm™ Temperature Measurement System consists of a multi-channel electronic temperature monitor (T-Box™) and single-use thermocouple-based temperature probes (T-Probe™).

Materials

All materials used in the manufacture of the VivaTherm™ Temperature Measurement System are suitable for this use and have been used in numerous previously cleared products.

Testing

Bench testing of the VivaTherm™ Temperature Measurement System confirmed similar performance as compared to a predicate device.

Summary of Substantial Equivalence

The VivaTherm™ Temperature Measurement System is equivalent to the predicate devices. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2003

Mr. Steven Kim
Vice President, Research & Development
Vivant Medical, Incorporated
1916-A Old Middlefield Way
Mountain View, California 94043

Re: K031556
Trade/Device Name: VivaTherm™ Temperature Measurement System
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL, BWX
Dated: May 16, 2003
Received: May 21, 203

Dear Mr. Kim:

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 Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUN 2 3 2003

Indications for Use

510(k) Number (if known):	This application
Device Name:	VivaTherm™ Temperature Measurement System
Indications for Use:	The VivaTherm™ Temperature Measurement System is intended to monitor tissue temperatures during clinical procedures requiring temperature feedback.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031556