K990416

DEC 23 1999

510(k) Summary

Date of Summary Preparation: January 29, 1999

Manufactures Contact Person:

Mark Fauci
President
Tel. (516)-444-6499
Fax. (516)-444-8825
OmniCorder Technologies, Inc.
25 East Loop Road
Stony Brook, NY 11790

Trade Name: OmniCorder BioScan System

Classification Name, Classification Number, Class, Classification Reference:

Classification Name	Class. No.	Class	21CFR §
Telethermographic System	IYM/LHQ	I	884.2980

Special Controls: There are no regulatory standards or special controls applicable for this device.

Indications for Use: The OmniCorder BioScan System is thermal camera based imaging device intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal.

The device is for adjunctive diagnostic screening for detection of breast cancer or other uses. This device is intended for use by qualified healthcare personnel trained in its use.

Device Description: The OmniCorder BioScan System is an infrared camera device which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings; and in the home. It is a prescription device intended for use only by health care professionals.

The captured energy is processed by software to produce digital output values of the thermal energy captured by the camera's thermal sensors.

The following accessories are available for use with the device:

1) Computer Processing Unit (Pentium II Workstation)
2) Color Monitor
3) Color Printer
4) Tripod Stand

The device and its accessories are similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

Substantially Equivalent Commercially Available Devices: OmniCorder BioScan System is substantially equivalent to the following commercially available predicate devices with respect to indications for use, device design, materials, and method of manufacture.

Substantial Equivalence Comparison: The : OmniCorder BioScan System is similar to commercially available devices with respect to intended use, material, design and operational principles as follows:

Inframetrics, Inc., Inframetrics Infracam-Med ~ (K982327)

Bales Scientific, Inc., BSI Model Tip ~ (K897191)

JEOL Model #JTG-500M ~ (K823041)

DCATS by Dorex Inc. ~ (K812799)

1. Operational Principles: The basic operational principles of the OmniCorder BioScan System and the predicate devices measure and record, without touching the patient's skin, self-emanating infrared radiation to reveal temperature variations. The parameters that are measured and displayed are generally the same as those for the predicate devices.

2. Indications and Contraindications: Relative indications and contraindications for the OmniCorder BioScan System and commercially available devices for similar intended uses are the same.

Assessment of non-clinical performance data for equivalence: Currently there are no FDA standards for this device. However, the OmniCorder BioScan System complies with:

CSA Standard C22.2, No. 125-1984, Electromedical Equipment

UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, OmniCorder Technologies concludes that the new device, the OmniCorder BioScan System, is safe, effective and substantially equivalent to the predicate device as described herein.

Table 1

Feature	BioScan System	InfraCam-Med (K982327)	BSI Model TIP (K897191)	Jeol Model# JTG-500M (K823041)	DCATS (K812799)
Intended Use	Visualization/ documentation of temperature patterns and changes	Visualization/ documentation of temperature patterns and changes	Visualization/ documentation of temperature patterns and changes	Visualization/ documentation of temperature patterns and changes	Visualization/ documentation of temperature patterns and changes
Method of Data Collection	Non-contact Passive Infrared Emissions	Non-contact Passive Infrared Emissions	Non-contact Passive Infrared Emissions	Non-contact Passive Infrared Emissions	Non-contact Passive Infrared Emissions
Collection Instrument	Infrared Camera	Infrared Camera	Infrared Camera	Infrared Camera	Infrared Camera
Data Processing	CPU/Custom Algorithms	CPU/Custom Algorithms	CPU/Custom Algorithms	CPU/Custom Algorithms	CPU/Custom Algorithms
Storage	Hard Disk	PCM/CIA card	Hard disk	Video tape	Hard disk
Detector Type	Focal Plane Array	Focal Plane Array	Single Detector	Single Detector	Single Detector
Display	Monitor/TV Printer	Monitor/TV Printer	Monitor/TV Printer	Monitor/TV Printer	Monitor/TV Printer
User interface	Keyboard, Mouse, On-system controls	On-system controls	Keyboard, Mouse, On-system controls	Keyboard, On-system controls	Keyboard, On-system controls

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1999

Mark Fauci
OmniCorder Technologies, Inc.
25 East Loop Road
Stony Brook, New York 11790

Re: K990416
OmniCorder BioScan System
Dated: September 18, 1999
Received: September 29, 1999
Regulatory Class: I
21 CFR 884.2980/Procode: 90 LHQ

Dear Mr. Fauci:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K990416

Device Name : OmniCorder BioScan System

Indications for Use:

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990416

Prescription Use ✓
(Per 21 CFR 801.109)