K033967

MAR - 9 2004

6.1 510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

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December 19, 2003

Flir Systems, Inc.
16 Esquire Road
North Billerica, MA 01862

Tel (978) 901-8227
Fax (978) 901-8532

Official Contact: Tom Scanlon

Proprietary or Trade Name: Series A, E, S, and P - IR cameras

Common/Usual Name: Telethermographic system

Classification Name: Telethermographic system (adjunctive use)

Predicate Devices:

Technology
Inframetrics, Inc.
Infracam-Med – K982327

Indications of Use
Dorex, Inc.
Spectrum 9000mb – K023434

Device Description: Flir manufactures a number of IR camera's, they all include the same basis temperature measurement and sensing technology. They are non-contacting and employ passive infrared emissions for sensing temperature variations.

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

Intended Use: The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes

Environment of Use: Hospital, Sub-acute Institutions, public areas, i.e., airports

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General Technical Characteristics

Attribute	Proposed devices – Series – A, E, S, P
Indications for use	The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes
Prescription	No
Intended population	Not applicable
Intended Environment of Use	Hospital, Sub-acute Institutions, public areas, i.e., airports
Design	
Method of data collection	Non-contacting detection of passive infrared emissions
Data processing	CPU
Detector type	Focal Plane Array
Display	Monitor or LCD
Temperature ranges	-40 °C to + 250 °C
Accuracy	±2 °C or ± 2% of reading
Materials	
Not applicable	Device is non-contacting
Performance Standards	
Under Section 514	None
Complies with various ISO standards	EMC, EMI

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed device is safe, effective, and substantially equivalent when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Flir Systems, Inc.
% Mr. Paul Dryden
President
ProMedic, Inc.
6329 W. Waterview Ct.
MCCORDSVILLE IN 46055-9501

Re: K033967
Trade/Device Name: Telethermographic camera
Series A, E, P, and S
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: 90 LHQ
Dated: December 19, 2003
Received: December 22, 2003

Dear Mr. Dryden:

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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6.3 Indications for Use

510(k) Number: K033967 (To be assigned)

Device Name: Telethermographic camera
Series A, E, P, and S

Intended Use: The Flir devices are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes.

Environment of use: hospital, sub-acute, public areas, i.e., airports

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033967