6.1 510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness
Page 1 of 2
December 19, 2003

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

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
### General Technical Characteristics

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Proposed devices – Series – A, E, S, P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>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</td>
</tr>
<tr>
<td>Prescription</td>
<td>No</td>
</tr>
<tr>
<td>Intended population</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Intended Environment of Use</td>
<td>Hospital, Sub-acute Institutions, public areas, i.e., airports</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td><strong>Method of data collection</strong></td>
</tr>
<tr>
<td></td>
<td>Non-contacting detection of passive infrared emissions</td>
</tr>
<tr>
<td></td>
<td>CPU</td>
</tr>
<tr>
<td>Data processing</td>
<td>Focal Plane Array</td>
</tr>
<tr>
<td>Display</td>
<td>Monitor or LCD</td>
</tr>
<tr>
<td>Temperature ranges</td>
<td>-40 °C to + 250 °C</td>
</tr>
<tr>
<td>Accuracy</td>
<td>±2 °C or ± 2% of reading</td>
</tr>
<tr>
<td>Materials</td>
<td>Device is non-contacting</td>
</tr>
<tr>
<td>Performance Standards</td>
<td>None</td>
</tr>
<tr>
<td>Under Section 514</td>
<td>None</td>
</tr>
<tr>
<td>Complies with various ISO standards</td>
<td>EMC, EMI</td>
</tr>
</tbody>
</table>

### 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.
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:

<table>
<thead>
<tr>
<th>Regulation Number</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>8xx.1xxx</td>
<td>(301) 594-4591</td>
</tr>
<tr>
<td>876.2xxx, 3xxx, 4xxx, 5xxx</td>
<td>(301) 594-4616</td>
</tr>
<tr>
<td>884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx</td>
<td>(301) 594-4616</td>
</tr>
<tr>
<td>892.2xxx, 3xxx, 4xxx, 5xxx</td>
<td>(301) 594-4654</td>
</tr>
<tr>
<td>Other</td>
<td>(301) 594-4692</td>
</tr>
</tbody>
</table>

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
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: [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 / Over-the-counter use
(Per CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number [To be assigned]