K073581

510(K) SUMMARY
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

510(k) number:

JUL 11 2008

1. Submitter's Identification:
Texas Infrared
2105 West Cardinal Drive
Beaumont, TX 77705
Contact: Gary Strahan
President/CEO
Phone: 409-861-0788
FAX: 409-866-7229
Date Summary Prepared: 7-27-2007

2. Name of the Device:
Common Name: Telethermographic System (Adjunctive Use)
Trade or Proprietary Name: ICI P and S Series IR Camera(s) and the IR Flash Software version 1.0
Device Class: 1
Product Code: LHQ
Regulation Number: 884.2980

4. Predicate Device Information:

Trade Name: A20M
FLIR Systems, Inc.
27700A SW Parkway Avenue
Wilsonville, OR 97070 USA
Phone: +1 800 322.3731
Fax: +1 503.498.3904
510(k) number: K033967

5. Device Description:

The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature.

Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airport.

ICI P and S Series Cameras

Base IR Camera	***ICI P and S series Cameras***
Intended Use	The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airport.
Technology	FPA uncooled Microbolometer
Material	Vanadium Oxide
Spectral Response	8 - 14 um
Contrast/Brightness	Software Controlled
Spatial Resolution IFOV	1.13 mrad
Data Output	Digital USB 2.0
Thermal Time Constant	14 ms
Thermal Sensitivity	0.038C @ 25C
Accuracy	+2C or 2%
Emissivity Correction	Computer Controlled
Performance	38 mK NETD
Frame Rate	S Series Camera 50-60fps P Series Camera < 9 fps
Pitch Size	25 um
Encapsulation	IP54
Optics	25mm with 22° FOV
Vibration	3G's
Shock	30G's
Array size	320 x 240 array
Weight	5.2oz (148g) w/lens
Tripod Mount	1/4" - 20 female thread
Operating Temperature	-20C to +50C
Storage Temperature	-40C to +70C
Dimensions	2.1"x3.2"x0.5"
Focus	Manual
Special Computer Hardware	USB 2.0 Compatible running Windows XP or Windows Vista. 64-bit operating systems are not supported at this time.
Power Supply	5 VDC @ 500ma max draw from USB. Systems with motorized focus have an additional 12 VDC supply @ 1A max.

Components of the system include:

ICI P or S Series IR Camera
USB Cable
Tripp-Lite model IS250HG isolation transformer

6. Intended Use:

The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature.

Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airport.

7. Comparison to Predicate Devices:

Technical characteristics of the device(s) compared to the predicate device:

Base IR Camera	**ICI P and S Series IR Camera(s) and the IR Flash Software version 1.0**	**A20M (K033967)**
Intended Use	The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airport.	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
Technology	FPAuncooled Microbolometer	FPA uncooled Microbolometer
Material	Vanadium Oxide	Amorphus Silica
Spectral Response	8 -14 um	7.5 -13um
Contrast/Brightness	Software Controlled	Manual or Software Controlled
Spatial Resolution IFOV	1.13 mrad	2.7 mrad
Data Output	Digital USB 2.0	RS170 EIA/NTSC or CCIR/PAL composite
Thermal Time Constant	14 ms	Unknown
Thermal Sensitivity	0.038C @ 25C	0.120C @ 30C
Accuracy	+2C or 2%	+2C or 2%
Emissitivity Correction	Computer Controlled	Variable from 0.1 to 1.0
Performance	38 mK NETD	Under <80mK

Frame Rate	S Series Camera 50-60fps P Series Camera < 9fps	60 fps
Pitch Size	25 um	Unknown
Encapsulation	IP54	IP40
Optics	25mm with 22° FOV	25mm with 19° FOV
Vibration	3G's	2G's
Shock	30G's	25G's
Array size	320 x 240 array	320 x 240 array
Weight	5.2oz (148g) w/lens	1.7lbs (0.8 kg)
Tripod Mount	1/4" -20 female thread	1/4" -20 female thread
Operating Temperature	-20C to +50C	-15C to +50C
Storage Temperature	-40C to +70C	-40C to +70C
Dimensions	2.1"x3.2"x0.5"	6.2"x2.9"x3.1"
Focus	Manual	Manual or Software Controlled
Special Computer Hardware	USB 2.0 Compatible running Windows XP or Windows Vista. 64-bit operating systems are not supported at this time.	Ethernet connection, Video capture device to vonvert RS-170 video, Firewire 8/16-bit monochrome and 8-bit color
Power Supply	5 VDC @ 500ma max draw from USB. Systems with motorized focus have an additional 12 VDC supply @ 1A max.	AC adaptor 110/220 vac, 50/60hz input to 12/24vdc nominal, <6w output

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The devices have been tested and found to comply with IEC-60601-1 and IEC 60601-1-2. Software validation was performed.

9. Discussion of Clinical Tests Performed:

Not applicable

10. Conclusions:

The subject device(s) has the same intended use and similar characteristics as the predicate device. Moreover, documentation supplied in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the ICI P and S Series IR Camera(s) and the IR Flash Software version 1.0 are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2008

Texas Infrared
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K073581
Trade/Device Name: ICI P and S Series IR Camera(s) and the IR Flash Software version 1.0
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: I
Product Code: LHQ
Dated: June 27, 2008
Received: June 30, 2008

Dear Mr. Lehtonen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

INDICATIONS FOR USE

510(k) Number (if known): K073581

Device Name : ICI P and S Series IR Camera(s) and the IR Flash Software version 1.0

Indications for Use:

The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature.
Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.

Prescription Use __X__ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073581