

AUG 18 1998

510(k) Summary
for
Inframetrics InfraCAM-MED

1. **COMPANY NAME AND ADDRESS**

Applicant Name and Address

Inframetrics, Inc.
16 Esquire Road
North Billerica, MA 01862-2598

Contact Person

Michael Paulding, Medical Products Manager
781-670-5555

Date of Summary Preparation

July 1, 1998

2. **DEVICE NAME**

Proprietary Name:	Inframetrics InfraCAM-MED
Common/Usual Name:	Thermographic Camera System
Classification Name:	Telethermographic System Surgical Camera and Accessories

3. **IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED**

The Inframetrics InfraCAM-MED is substantially equivalent to several legally marketed infrared thermography systems, such as the Opgal IVA-2000 distributed by OPGAL (K951806), and the Inframetrics Model 535 Infrared Medical Thermography System (K822729).

4. DEVICE DESCRIPTION

The InfraCAM-MED is a small infrared camera with integral high-resolution CRT viewfinder. It is a battery operated thermal imaging system that is completely self contained with integral TV compatible display. The InfraCAM-MED is qualified to MIL_STD 810E. The camera head houses the thermal image camera. During surgery, the camera is situated outside the sterile field therefore it is not covered by a sterile drape.

5. INTENDED USE

The InfraCAM-MED is a non-contact, non-invasive, non-radiating, thermal (infrared) imaging video camera intended as an adjunctive diagnostic device for viewing heat patterns generated by the relative surface temperature of human heart tissue and vessels during coronary artery bypass graft surgery. Images of the exposed heart may be captured as a black/white video image using VHS/SVHS videotape, or a black/white still image using a thermal image printer. The InfraCAM-MED Thermal Coronary Angiography imaging camera may be used to perform the following:

- Viewing and documenting temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by the injection of cold or warm fluid into the proximal end of a vein graft.
- Viewing and documenting temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by blood flow after release of the cross clamp(s) on a arterial graft.
- Viewing and documenting temperature changes to the myocardium during the retrograde or antegrade perfusion of warm or cold cardioplegia.

6. A Statement of How the Technological Characteristics of the Device Compare to Those of the Predicate or Legally Marketed Device(s) Cited

The Inframetrics InfraCAM-MED is substantially equivalent to the Opgal IVA-2000 and the Inframetrics Model 535 Infrared Medical Thermography System in intended use in that they all are intended to visualize and document temperature

patterns and temperature changes in tissue temperature during coronary artery bypass surgeries. In addition, the InfraCAM-MED is intended to view and document temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by the injection of cold or warm fluid into the proximal end of a vein graft, view and document temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by blood flow after release of the cross clamp(s) on an arterial graft, and view and document temperature changes to the myocardium during the retrograde or antegrade perfusion of warm or cold cardioplegia.

All three systems have various design features in common. Neither the InfraCAM-MED, the Model 535 Infrared Medical Thermography System nor the IVA-2000 is in direct contact with the patient. The systems vary in components and accessories. All three include a thermal image camera. The IVA-2000 and Model 535 include a CCD camera, videocassette recorder, and thermal printer while the InfraCAM-MED includes only the camera.

Unlike the IVA-2000 and the Model 535, the Inframetrics InfraCAM-MED does not allow image capture and storage for subsequent retention and/or review. The Inframetrics InfraCAM-MED and both predicate devices display images in real time with the capability for printing and recording. The IVA-2000 and the Model 535 use keyboard entry of relevant procedural data, such as patient identifiers. The Inframetrics InfraCAM-MED does not provide for data entry or overlay of information on the image whereas both the Model 535 and the IVA-2000 do both.

The InfraCAM-MED displays the thermal image in 256 shades of Black and White, whereas the IVA 2000 uses 256 shades of Black/White or Red/White. No color bar is utilized. The Model 535 is color selectable in 6, 10, 14, or 20 colors. Neither the proposed InfraCAM-MED nor the IVA-2000 displays the temperature of the target whereas the Model 535 displays temperature in degrees. The IVA-2000 is software controlled. The Inframetrics InfraCAM-MED and the Model 535 do not utilize a microprocessor for any function.

Additionally, both animal and clinical testing were performed using the InfraCAM-MED which showed that the InfraCAM-MED performs as intended.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Inframetrics, Inc.
c/o Mary McNamara-Cullinane
Medical Device Consultants
49 Plain Street
North Attleboro, MA 02760Re: K982327
Inframetrics InfraCAM-MED
Dated: July 1, 1998
Received: July 2, 1998
Regulatory class: I
21 CFR 884.2980/Procode: 90 LQH

Dear Ms. McNamara-Cullinane:

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 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,

Lillian Yin, Ph.D.
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 (if known): _____

Device Name: Inframetrics InfraCAM-MED

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gerard G. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982327

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)