FEB 2 0 2004

Exhibit # 1

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.

The assigned 510(k) number is: K032350

1. Submitter's Identification:

Infrared Sciences Corp.
380 Townline Road
Hauppauge, NY 11788

Contact: Mr. Anthony Trotta
Principal Engineer

Date Summary Prepared: July 29, 2003

2. Name of the Device:

Infrared Sciences BreastScan IR™ System

3. Predicate Device Information:

K#990416, OmniCorder BioScan System, OmniCorder Technologies, Inc., Stony Brook, NY

4. Device Description:

The BreastScan IR ™ System is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR ™ System has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

Components of the system include:

Infrared System Device

Color Inkjet Printer

TV/VCR

Medical Cart

BreastScan IR Server

Air Cooling Device

Patient Chair

5. **Intended Use:**

The Infrared Sciences BreastScan IR™ 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. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

6. **Comparison to Predicate Devices:**

A Comparison Chart Outlining Similarities and Differences Follows:

Feature	BreastScan IR™ System	BioScan System
Intended Use	Visualization/Documentation of Temperature Patterns and Changes – Adult Only	Visualization/Documentation of Temperature Patterns and Changes – Adult, Pediatric and Neonatal
Method of Data Collection	Non-Contact Passive Infrared Emissions	Non-Contact Passive Infrared Emissions
Collection Instrument	Infrared Camera	Infrared Camera
Data Processing	CPU with Custom Algorithms	CPU with Custom Algorithms
Measurement Parameters	Allows for Static and	Allows for Static

	Dynamic Measurement of Thermal Patterns	Measurement of Thermal Patterns
Storage	Hard Disk	Hard Disk
Detector Type	Focal Plane Array	Focal Plane Array
Detector Resolution	320 x 240 Pixels	256 x 256 Pixels
Thermal Sensitivity	0.08°C	0.05°C
Camera Output	14 Bit Digital	14 Bit Digital
Display	Monitor, TV, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-System Controls	Keyboard, Mouse, On-system Controls

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

The device will comply with IEC-60601-1 and IEC 60601-1-2. Software validation was performed.

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

The subject device 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 Infrared Sciences BreastScan IR™ System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Infrared Sciences Corp.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K032350
Trade/Device Name: Infrared Sciences BreastScan IR™ System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: 90 LHQ
Dated: December 17, 2003
Received: December 18, 2003

Dear Ms. Goldstein-Falk:

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

Exhibit B

510(k) Number (if known): K032350

Device Name: Infrared Sciences BreastScan IR™ System

Indications For Use:

The Infrared Sciences BreastScan IR™ 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. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** OR **Over-The Counter Use** _____ **(Optional Format 1-2-96)**

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032350