DEC 1 0 2004

K042679

## PREMARKET NOTIFICATION 510(K) SUMMARY

**Company:**

InfraRed Imaging Systems, Inc.
1275 Kinnear Road
Columbus, OH 43212-1155
Telephone: 614/675-3729
Fax: 614/487-3704

**Company Contact:**

Dale Siegel
1275 Kinnear Road
Columbus, Ohio 43212
614-675-3729
dsiegel@irimagesys.com

**Date:**

September 28, 2004

**Proposed Proprietary Trade Name:**

IR Viewer

**Classification :**

| Classification Name | Classification Section | Class | Panel | Product Code |
|---|---|---|---|---|
| Liquid crystal vein locator | 880.6970 | I | General Hospital | KZA |
| Transilluminator | 886.1945 | I | Ophthalmic | HJN |

**Device Description:**

The IR Viewer is a non-invasive, electronic medical device that provides visualization of patient vasculature to supplement normal, line-of-sight viewing of vascular structures.

**Intended Use:**

The IR Viewer is indicated for use in procedures for inserting a needle or catheter in superficial, peripheral vessels.

**Predicate Devices:**

ESP7 (Ironmaster)
Venoscope (Trinity Partners)

**Performance Data:**

Performance data were submitted to characterize the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2004

Dr. Dale Siegel
President
InfraRed Imaging Systems, Incorporated
1275 Kinnear Road
Columbus, Ohio 43212

Re: K042679
Trade/Device Name: IR Viewer
Regulation Number: 880.6970
Regulation Name: Liquid Crystal Vein Locator
Regulatory Class: I
Product Code: KZA
Dated: September 28, 2004
Received: September 29, 2004

Dear Dr. Siegel:

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 (240) 276-0115. 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 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## InfraRed Imaging Systems 510(k) Application

### Indications for Use Statement

510(k) Number (if known): K042679

Device Name: IR Viewer

Indications for Use:

The IR Viewer is a non-invasive, electronic device for visualization of patient vasculature to supplement normal, line-of-sight viewing of vascular structures. It is indicated for use in procedures for inserting a needle or catheter in superficial, peripheral vessels.

Prescription Use _____ or Over-The-Counter Use _____X_____.
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042679