

K 120949

510(k) SUMMARY

JAN 11 2013

InfraScan, Inc.'s Infrascanner Model 2000

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

InfraScan, Inc.
3508 Market Street
Philadelphia, PA 19104
Phone: 215-387-6784
Facsimile: 215-386-2327

Contact Person: Baruch Ben Dor, CEO

Date Prepared: January 11, 2013

Name of Device and Name/Address of Sponsor

Infrascanner Model 2000

InfraScan, Inc.
3508 Market Street
Philadelphia, PA 19104

Common or Usual Name

Near Infrared (NIR) Brain Hematoma Detector

Classification Name

OPT (21 C.F.R. §882.1935)

Predicate Devices

InfraScan's Infrascanner Model 1000 (K080377)

Intended Use / Indications for Use

The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of greater than 3.5 mL in volume that are less than 2.5 cm from the brain surface, as an adjunctive device to the clinical evaluation in the acute hospital setting of patients 18 years old or greater with suspected traumatic supratentorial intracranial hematoma. The device is indicated to assess patients for CT scans but should not serve as a substitute for these scans. The Infrascanner is indicated for use by Physicians, or under the direction of a physician, who has been trained in the use of the device.

Technological Characteristics

The Infrascanner Model 2000 is a noninvasive device, which uses near-infrared spectroscopy (“NIRS”) to provide early information about the possible development of traumatic supratentorial intracranial hematomas in patients presenting to hospitals with head trauma. This technology involves comparing regional differences in absorbance of NIR light. The application of NIRS to hematoma evaluation is based on the principle that intracranial hemoglobin concentration will differ where a hematoma is present, compared to hemoglobin concentrations in normal intracranial regions. The system consists of a Class I NIR-based sensor. The sensor is optically coupled to the patient’s head through two disposable light guides in a “hairbrush” configuration. Examination with the Infrascanner is performed through placement of the sensor on designated areas of the head that represent the most common locations for traumatic hematoma. The examination is designed to be performed within two minutes.

Performance Data

Bench testing demonstrated that the Infrascanner Model 2000 functioned as intended. Testing comparing the Infrascanner Model 2000 and its predicate was conducted using a multilayer brain hematoma model to provide an approximation of human tissue. Results with the multilayer model for both the Model 2000 and the predicate were consistent with the expected result observed in clinical testing of the predicate. Performance was substantially similar for both models across a range of depths and sizes of hematomas similar to those seen in the clinical setting, and for light and dark skin types. Additional laboratory testing demonstrated the comparability of the device and its predicate over the range of optical densities observed in the clinical setting.

Substantial Equivalence

The Infrascanner Model 2000 is as safe and effective as the Infrascanner Model 1000. The Infrascanner Model 2000 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Infrascanner Model 2000 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Infrascanner Model 2000 is as safe and effective as the Infrascanner Model 1000. Thus, the Infrascanner Model 2000 is substantially equivalent.



January 11, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Hogan Lovells US LLP
% Steven B. Datlof, M.D., J.D.
Official Correspondent
InfraScan, Incorporated
1835 Market Street, 2 9th floor
Philadelphia, PA 19103

Re: K120949

Trade/Device Name: Infrascanner Model 2000
Regulation Number: 21 CFR 882.1935
Regulation Name: Near Infrared (NIR) Brain Hematoma Detector
Regulatory Class: Class II
Product Code: OPT
Dated: December 13, 2012
Received: December 13, 2012

Dear Dr. Datlof:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Deborah L. Falls

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120949

Device Name: Infrascanner Model 2000

Indications for Use:

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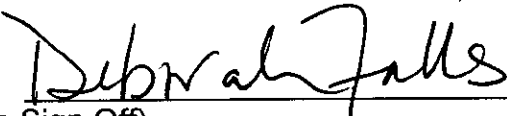
Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

<p> _____ (Division Sign Off) Division of Neurological and Physical Medicine Devices (DNPMD)</p> <p>510(k) Number <u> K120949 </u></p>
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