December 12, 2024

Infrascan, Inc.
Baruch Ben Dor
President & CEO
3508 Market Street, Suite 127
Philadelphia, Pennsylvania 19104

Re: K241389
Trade/Device Name: Infrascanner Model 2500 (Model 2500)
Regulation Number: 21 CFR 882.1935
Regulation Name: Near Infrared (NIR) Brain Hematoma Detector
Regulatory Class: Class II
Product Code: OPT
Dated: May 15, 2024
Received: November 12, 2024

Dear Baruch Ben Dor:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241389

Device Name
Infrascanner Model 2500 (Model 2500)

Indications for Use *(Describe)*
The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of as small as 3.5mL and as deep as 2.5 cm from brain surface, but not both at the same time, as an adjunctive device to the clinical evaluation in the acute hospital setting of adult patients and pediatric patients aged 2 years and older 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 device should only be used to rule in subjects for the presence of hematoma, never to rule out. 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional Premarket Notification Submission – 510(k)

Infrascanner Model 2500 510(k) Number K241389

Date Prepared: November 8, 2024

I. SUBMITTER

Infrascan, Inc.
3508 Market Street
Philadelphia PA 19104

Contact Person
Baruch Ben Dor, PhD
Infrascan, Inc.
3508 Market Street
Philadelphia PA 19104
Tel: (610) 387-6784
bbendor@infrascanner.com

II. DEVICE

Name of Device:	Infrascanner Model 2500
Common or Usual Name:	Near Infrared (NIR) Brain Hematoma Detector
Classification Name:	21 CFR § 882.1935 - Near Infrared (NIR) Brain Hematoma Detector Product Code OPT
Regulatory Class:	II

III. PREDICATE DEVICE

- Infrascan, Inc. Infrascanner Model 2500 cleared under K211617, Product Code: OPT

IV. DEVICE DESCRIPTION

The device 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.

V. INDICATIONS FOR USE

The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of as small

as 3.5mL and as deep as 2.5 cm from brain surface, but not both at the same time, as an adjunctive device to the clinical evaluation in the acute hospital setting of adult patients and pediatric patients aged 2 years and older 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 device should only be used to rule in subjects for the presence of hematoma, never to rule out. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Infrascanner Model 2500 is the same device as the predicate Model 2500 except for an upgrade of laser power from 100 mW to 200 mW to enable readings in very dark-skinned people.

As illustrated in Table 1, the subject device has the same indication for use, technological characteristics, and principles of operation as its predicate device. The enhancement of increased laser power raises no new issues of safety or effectiveness as demonstrated by clinical performance data and bench data and is substantially equivalent.

Table 1: Substantial Equivalence

	Model 2500 K211617 (predicate)	**Upgraded Model 2500 (subject device)**	**Equivalence**
Indications for Use	The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of as small as 3.5mL and as deep as 2.5 cm from brain surface, but not both at the same time, as an adjunctive device to the clinical evaluation in the acute hospital setting of adult patients and pediatric patients aged 2 years and older 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 device should only be used to rule in subjects for the presence of hematoma, never to rule out. 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.	The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of as small as 3.5mL and as deep as 2.5 cm from brain surface, but not both at the same time, as an adjunctive device to the clinical evaluation in the acute hospital setting of adult patients and pediatric patients aged 2 years and older 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 device should only be used to rule in subjects for the presence of hematoma, never to rule out. 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.	Identical
Target population	Brain injury victims more than 2 years old	Brain injury victims more than 2 years old	Identical
Method of Measurement	Measures tissue hemoglobin concentration using NIRS	Measures tissue hemoglobin concentration using NIRS	Identical
Probe placement	Over frontal, temporal, parietal, occipital regions of brain	Over frontal, temporal, parietal, occipital regions of brain	Identical
Data processor	Microcontroller unit (MCU)	Microcontroller unit (MCU)	Identical

	Model 2500 K211617 (predicate)	Upgraded Model 2500 (subject device)	Equivalence
Communication between patient-contacting unit and data processor	Serial port protocol over wired connection	Serial port protocol over wired connection	Identical
System display	Built-in display	Built-in display	Identical
User interface	Membrane button- controlled software	Membrane button- controlled software	Identical
Power source	Rechargeable Lithium Polymer 3.7V battery or 2 disposable AA batteries	Rechargeable Lithium Polymer 3.7V battery or 2 disposable AA batteries	Identical
Power switch	Disposable Shield activated On/Off electrical switch	Disposable Shield activated On/Off electrical switch	Identical
Patient interface	Two disposable 1.6 mm PMMA fibers, 4 cm from each other	Two disposable 1.6 mm PMMA fibers, 4 cm from each other	Identical
Light source	100 mW, 808 nm Diode Laser	200 mW, 808 nm Diode Laser	Substantially equivalent
Laser control and safety	Pulsing with dedicated fuse for overpower and pulsing failure	Pulsing with dedicated fuse for overpower and pulsing failure	Identical
Detector + optical filter	Silicon detector + 808 nm filter	Silicon detector + 808 nm filter	Identical
Signal processing, control algorithm and results display	Automatic algorithm to control hardware, graphical and numerical display. Hematoma detection threshold of ΔOD = 0.2.	Automatic algorithm to control hardware, graphical and numerical display. Hematoma detection threshold of ΔOD = 0.2.	Identical

VII. PERFORMANCE DATA

The following clinical testing and non-clinical testing was conducted to demonstrate the appropriate substantial equivalence of the Infrascanner Model 2500 to the predicate.

Phantom Testing

A skin color test was performed using a phantom head model. Test data were collected using filters to model three skin color groups for various hematoma size and depths. Measurements were made using the 100mW and 200mW scanners. The test data sets established that the Infrascanner Model 2500 had substantially equivalent performance between 200mW and 100mW laser power settings across a range of simulated hematoma sizes and depths and for light-skinned to very dark-skinned people.

Laser Power Performance Comparability Protocol

Five (5) Model 2500 scanners were used to perform optical density measurements across a range of different attenuations at 200mW and 100mW. The difference between models met the acceptance criteria and was less than 5% in absolute OD.

IEC Testing

Other bench testing the following testing with acceptable results for all tests: IEC 60601-1; IEC 60601-1-2; AIM 7351731 RFID Immunity; and IEC 60825-1.

Clinical Performance

Duke University Global Neurosurgery studied the Infrascanner in Mbarara hospital in Uganda. The study evaluated 672 consecutive patients with confirmed or suspected head trauma who received a head CT scan. Overall Infrascanner and CT data were available for 387 patients. Table 2 includes the demographics and the injury description of the whole analyzed cohort of 387 patients.

Table 2: Patient Baseline Demographics

		N	%
Gender	Male	341	88.1%
	Female	46	11.9%
Age	Range (Mean)	12-78 (32.8)	
Glasgow Coma Scale (GCS)	Mild	273	70.5%
	Moderate	52	13.5%
	Severe	46	11.9%
	Critical	16	4.1%
Mortality by GCS	Mild	3	1.1%
	Moderate	4	7.7%
	Severe	8	17.4%
	Critical	11	68.8%
Mechanism of Injury	RTA	298	77.0%
	Assault	66	17.1%
	Fall	11	2.8%
	Other	6	1.6%
	Accidental injury	4	1.0%
	Unknown	2	0.5%
Mortality	No	361	93.3%
	Yes	26	6.7%
Face or Scalp Hematoma Present	No	99	25.6%
	Yes	283	73.1%
Visible Bleeding (Eye, Ear, Nose)	No	170	43.9%

After removing patients with small contusions outside of the range of the Infrascanner, 138 patients had bleeding within the detection abilities of the Infrascanner. Of these 138 patients, 71 patients were randomly selected to receive measurements with both 100 mW and 200 mW Infrascanners. Table 3 presents the Infrascanner performance (sensitivity, specificity, positive and negative predictive values) for the above patient sub-groups: 345 patients with 138 hematomas within the detection range of the Infrascanner, measured by 100mW scanner, the selected 71 patients measured with 100mW and the same selected 71 patients measured with 200mW scanner. Three of the 71 patients had very dark skin.

Table 3: Infrascanner Detection Performance of Hematomas Within the Detection Range of the Device

	100mW in 345 patients' group	100mW in 71 patient's subgroup	200mW in 71 patient's subgroup
Number of patients	345	71	71
Hematomas within detection range	138	30	30
Sensitivity	91.3%	100.0%	96.7%
CI	85.3-95.4	88.4-100	82.8-99.9
Specificity	39.1%	36.6%	43.9%
CI	32.4-46.1	22.1-53.1	28.5-60.3
Positive Predictive Value	50.0%	53.6%	55.8%
CI	43.7-56.3	39.7-67.0	41.3-69.5
Negative Predictive Value	87.1%	100.0%	94.7%
CI	78.5-93.2	78.2-100	74.0-99.9

Based on the results of this study, the clinical performance of the Infrascanner at 200mW laser power setting is substantially equivalent to the performance of the Infrascanner at 100mW laser power setting. The analysis of clinical data concluded that i) in patients with a detectable hematoma, the sensitivity of both laser power settings was equivalent, ii) in patients with no hematomas, the specificity in both laser power settings was equivalent, and iii) in three very dark skin individuals where measurements could not be collected with 100mW scanner, the proposed 200mW setting scanner was able to complete the measurements.

IX. CONCLUSION

Based on the same intended use, similar technological characteristics, acceptable performance testing, and clinical validation the modified device is substantially equivalent to the predicate and raises no additional or different questions of safety or effectiveness