February 9, 2022

InfraScan, Inc.
% Angela Mallery
Principal Product Development Strategist
NAMSA
400 US-169
Minneapolis, Minnesota 55441

Re: K211617
Trade/Device Name: Infrascanner
Regulation Number: 21 CFR 882.1935
Regulation Name: Near Infrared (NIR) Brain Hematoma Detector
Regulatory Class: Class II
Product Code: OPT
Dated: January 6, 2022
Received: January 10, 2022

Dear Angela Mallery:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

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)*
K211617

Device Name
Infrascanner

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.

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510(k) SUMMARY

K211617

Date	February 9, 2022
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
Name/Address of Sponsor	InfraScan, Inc. 3508 Market Street Philadelphia, PA 19104
Name of Device	Infrascanner Model 2000 and 25000
Common or Usual Name	Near Infrared (NIR) Brain Hematoma Detector
Classification Name	OPT (21 C.F.R. §882.1935)
Predicate Devices	InfraScan Infrascanner K120949 (Model 2000) and K200203 (Model 2500)
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.
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.
Technological Characteristics	The device remain unchanged from the predicate clearances Bench testing comparing the subject device to the predicate using a pediatric laboratory model(s) of brain hematoma as compared to adult laboratory models. Testing included repeatability and reproducibility; agreement tests, and skin color tests; these results established device performance metrics across a range of simulated hematoma sizes, depths, and for light and dark skin and for bench hematoma models of adult and children 2 and above.

	Bench testing demonstrated that device functioned as intended. Testing comparing to the predicate was conducted using a hematoma model to provide an approximation of human tissue. Testing included repeatability and reproducibility. Results were consistent with the expected result. Performance was substantially similar for both models across a range of age groups, depths and sizes of hematomas, and for skin types. Additional laboratory testing demonstrated the comparability of the device and its predicate over the range of optical densities. Four types of tests were conducted in order to evaluate substantial equivalence • Repeatability / Reproducibility to assess the degree of agreement between measurements conducted on the same device. The repeatability and reproducibility test data involved repeat observations with three different systems for each of the two models. Model hematomas of 5 mL and 50 mL were evaluated at depths below the skull of shallow and deep ranges at 0 cm, and 3 cm • Agreement test to assess the degree of agreement between measurements conducted by Model 2000 and Model 2500. The agreement test data were collected for one system of each model for hematomas of size 5 mL and 50 mL • Skin color test to assess the effect of the skin color on the measurements conducted by Model 2000 and Model 2500. The evaluation of the potential impact of skin color was performed for both models with hematoma size of 5 mL at depths of 0 and 2 cm, and without a model hematoma in the tank • Pediatric test to assess the effect of age on the degree of agreement between measurements conducted by Model 2000 and Model 2500. The potential effect of age on the measurements by the two models was tested using one system of each model for hematomas of size 5mL and 50 mL at 0 and 3 cm depths, on the phantom side mimicking the head of a 6 months old A 4-corners approach was used the selection and testing of the hematoma size and depth and for the age groups • Small (5 ml) and large (50 ml) hematomas • Superficial (0 cm) and deep (2 and 3cm) hematomas • Adult (>18 years old) and infant (6 months old) ages were tested A mixed multi-layered solid and liquid optical head phantom mimicking human tissue was used in the test. For brain tissue optical parameters intralipid was used to control the scattering properties and a calibrated ink to control absorption properties. Modeled layers of skin, scalp, skull and CSF with the liquid brain layer and blood were used to simulate brain hematoma. Each of the phantom walls were built to mimic different age groups. Silicone was selected for building the phantom due to a close match to the mechanical properties of tissue. Carbon black was used as the absorbing agent, and Titanium Dioxide was used as the scattering agent. The optical absorption and scattering properties of each layer were confirmed further by optical frequency-domain measurement systems. The optical properties of the CSF layer were those of water. Thin neutral density (ND) Wratten 2 film filters were placed over the phantom to adjust the signal level to OD values observed in the clinical studies for patients with different skin color. The thickness of the film filters is similar to the thickness of human skin. Using those filters, the OD values in the new lab tests covered the range of OD to simulate light-skinned patients and OD to simulate dark skinned subjects. The attenuation values of the filters were selected to match the OD values observed in the clinical studies. The brain model was filled with water, intralipid for scattering and a black ink for absorption. This mixture created a simulation of brain tissue. Our approach is to use whole blood as a hematoma. A flat hematoma model was used in this test. The flat hematoma model was built using a rectangular frame, inserted into a ball, and filled with blood. The rectangular frame forced the shape of the hematoma to remain relatively flat.
Clinical data	A clinical study was carried out in the Emergency Departments large urban quaternary care academic medical centers on males or females aged 6 months – 18 years. 464 patients were enrolled and 344 met inclusion for primary data analysis. In these patients, 10.5% had evidence of a hematoma on HCT, and 4.7% had qualifying hematomas. This clinical study data was complemented with a literature review meta-analysis to provide the following age-specific performance estimates and confidence intervals in the newly indicated pediatric population subgroups with comparison to the predicate adult population performance estimates: Diagnostic performance was independent of age (divided by quartile), hair/skin color, and race. Diagnostic performance was independent of whether three (43% 149/344) or four (57% 195/344) brain regions were assessed.

<table>
<tr><td></td><td>
<table>
<tr><th colspan="4">Infrascanner performance in pediatric and adult subgroups</th></tr>
<tr><th></th><th>2-12 Years Old</th><th>12-18 Years Old</th><th>Adults K080377</th></tr>
<tr><td>Total</td><td>220</td><td>146</td><td>383</td></tr>
<tr><td>No Hematomas</td><td>202</td><td>139</td><td>320</td></tr>
<tr><td>Hematomas</td><td>18</td><td>7</td><td>63</td></tr>
<tr><td>Sensitivity</td><td>88.9%
65.3% to 98.6%</td><td>85.7%
42.1% to 99.6%</td><td>74.6%
62.1% to 84.7%</td></tr>
<tr><td>Specificity</td><td>72.3%
65.6% to 78.3%</td><td>73.4%
65.2% to 80.5%</td><td>81.6%
76.9% to 85.7%</td></tr>
<tr><td>PPV</td><td>22.2%
17.8% to 27.4%</td><td>14.0%
9.7% to 19.6%</td><td>44.3%
37.8% to 51.1%</td></tr>
<tr><td>NPV</td><td>98.6%
95.2% to 99.6%</td><td>99.0%
94.3% to 99.8%</td><td>94.2%
91.4% to 96.2%</td></tr>
</table>
PPV – Positive Predictive Value, NPV – Negative Predictive Value.
Sensitivity, specificity, PPV and NPV values include also the 95% confidence intervals</td></tr>
<tr><td>Substantial Equivalence</td><td>The subject device is as safe and effective as the predicate device. The subject device has the same intended for use, technological characteristics, and principles of operation as its predicate device. Bench data demonstrate the subject device performance in pediatric subjects is substantially equivalent to the performance in adult subjects of the predicate.</td></tr>
<tr><td>Conclusion</td><td>The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate</td></tr>
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