



Food and Drug Administration
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DEC 20 2011

Re: K080377
Infrascanner Model 1000
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 882.1935
Regulation Name: Near Infrared (NIR) Brain Hematoma Detector
Regulatory Classification: Class: II
Product Code: OPT
Dated: April 8, 2010
Received: April 8, 2010

Dear Dr. Datlof:

This letter corrects our classification letter of December 13, 2011.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the Infrascanner Model 1000, a prescription device under 21 CFR Part 801.109 that 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 hematomas. The device is indicated to assess patients for CT scans but should not serve as a substitute for these scans. The Infrascanner Model 1000 is indicated for use by physicians, or under the direction of a physician, who have been trained in the use of the Infrascanner Model 1000. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Infrascanner Model 1000, and substantially equivalent devices of this generic type, into class II under the generic name, Near Infrared (NIR) Brain Hematoma Detector.

FDA identifies this generic type of device as:

Near Infrared (NIR) Brain Hematoma Detector - a noninvasive device that employs near-infrared spectroscopy that is intended to be used to evaluate suspected brain hematomas.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 16, 2010 automatically classifying the Infrascanner Model 1000 in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On April 8, 2010, FDA filed your petition requesting classification of the Infrascanner Model 1000 into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Infrascanner Model 1000 into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition and in response to our November 1, 2011 telecon, FDA has determined that the Infrascanner Model 1000 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 hematomas. The device is indicated to assess patients for CT scans but should not serve as a substitute for these scans. The Infrascanner Model 1000 is indicated for use by a physician, or under the direction of a physician, who have been trained in the use of the device.”

This device can be classified in class II with the establishment of special controls and FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

Table 1. Potential Risks and Mitigations

Identified Risk	Mitigation Measures
Excessive laser power	Electrical Safety and Electromagnetic Compatibility
Interference with other devices	Electrical Safety and Electromagnetic Compatibility Labeling
Unit (hardware) malfunction	Performance Testing (non-clinical and clinical) Software Verification, Validation and Hazard Analysis
Software malfunction	Software Verification, Validation and Hazard Analysis
Operator errors	Labeling Training
Incorrect result (false positive and negative)	Labeling
Adverse tissue reaction	Biocompatibility
Battery failure (Failure of device to operate)	Labeling

In addition to the general controls of the FD&C Act, the Near Infrared (NIR) Brain Hematoma Detector is subject to the following special controls: (1) The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 of this chapter; (2) The labeling must include specific instructions and the clinical training needed for the safe use of this device; (3) Appropriate analysis/testing should validate electromagnetic compatibility (EMC), electrical safety, and battery characteristics; (4) Performance data should validate accuracy and precision and safety features; (5) Any elements of the device that may contact the patient should be demonstrated to be biocompatible; and, (6) Appropriate software verification, validation, and hazard analysis should be performed.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who

intend to market this device type must submit to FDA a premarket notification containing information on the Near Infrared (NIR) Brain Hematoma Detector they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Daryl L. Kaufman at 301-796-6467.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jonette Foy".

Jonette Foy, Ph.D.
Deputy Director
Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health