comment period, we intend to publish a document in the **Federal Register** confirming the effective date within 30 days after the comment period ends.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not impose any significant costs, we certify that it will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. We do not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

We have concluded that this direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

V. Environmental Impact

We have determined under 21 CFR 25.33 that this direct final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this direct final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded this direct final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document, and they may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 20 is amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 2. Amend § 20.108 as follows:
■ a. Revise paragraph (b);
■ b. Remove paragraph (c);
■ c. Redesignate paragraph (d) as paragraph (c);
■ d. Revise newly redesignated paragraph (c).

The revisions and redesignations read as follows:

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

* * * * *

(b) All written agreements and memoranda of understanding between FDA and any entity, including, but not limited to other departments, Agencies, and organizations will be made available through the Food and Drug Administration Web site at *http://www.fda.gov* once finalized.

(c) Agreements and understandings signed by officials of FDA with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraph (b) of this section. Although such agreements and understandings will not be made available through the FDA Web site, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6967 Filed 3–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2012–M–0206]

Medical Devices; Neurological Devices; Classification of the Near Infrared Brain Hematoma Detector

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Near Infrared (NIR) Brain Hematoma Detector into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective April 23, 2012. The classification is applicable beginning December 13, 2011.

FOR FURTHER INFORMATION CONTACT: Daryl Kaufman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2426, Silver Spring, MD 20993–0002, 301–796–6467.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), 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 predicate 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 regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will 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** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 16, 2010, classifying the Infrascanner into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On April 8, 2010, InfraScan, Inc. submitted a petition requesting classification of the Infrascanner Model 1000 under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special 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, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name Near Infrared (NIR) Brain Hematoma Detector, and it is identified as a noninvasive device that employs near-infrared spectroscopy that is intended to be used to evaluate suspected brain hematomas.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

Identified risk	Mitigation measures
Excessive laser power	Electrical safety and electromagnetic compatibility (EMC).
Interference with other devices	Electrical safety and EMC. Labeling.
Unit (hardware) malfunction	Performance testing (nonclinical 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.

FDA believes that the following special controls address these risks to health and provide reasonable assurance of safety and effectiveness: (1) The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109; (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 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. Therefore, on December 13, 2011, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 882.1935.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an NIR Brain Hematoma Detector will need to comply with the special controls named in the regulation.

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. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the NIR Brain Hematoma Detector they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain State requirements ''different from or in addition to'' certain Federal requirements applicable to devices. 21 U.S.C. 360k; see *Medtronic, Inc.,* v. *Lohr,* 518 U.S. 470 (1996), and *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). The special controls established by this final rule create ''requirements'' under 21 U.S.C. 360(k).

V. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from InfraScan, Inc., April 8, 2010.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 882.1935 is added to subpart B to read as follows:

§ 882.1935 Near Infrared (NIR) Brain Hematoma Detector.

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

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 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.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6975 Filed 3–22–12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0132]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Broadway Bridge across the Willamette River, mile 11.7, at Portland, OR. This deviation is necessary to accommodate the Race for the Roses event scheduled for April 1, 2012. This deviation allows the bridge to remain in the closed position to allow safe movement of event participants.

DATES: This deviation is effective from 6:30 a.m. on April 1, 2012 through 7:30 a.m. April 1, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2012–0132 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0132 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or