That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Monroe City Regional Airport and within 3.5 mules each side of the Quincy VORTAC 239° radial extending from 6.3-mile radius to 7 miles northeast of the airport.

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Issued in Kansas City, MO, on February 8, 2001.

Richard L. Day,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 01–4677 Filed 2–27–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 00P–1675]

Clinical Chemistry and Clinical Toxicology Devices; Classification of B–Type Natriuretic Peptide Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the B-type natriuretic peptide (BNP) test system into class II (special controls). The special control that will apply to this device is a guidance document entitled ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: This rule is effective February 28, 2001.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the 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 (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 act, 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 act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

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

In accordance with section 513(f)(1) of the act, FDA issued an order on November 13, 2000, classifying the BNP test in 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 that was subsequently reclassified into class I or II. On November 15, 2000, FDA received a petition submitted by Biosite Diagnostic, Inc., requesting classification of the BNP test system into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Biosite Diagnostics BNP test system can be classified in class II with the establishment of special controls. This device is intended to measure BNP in whole blood and plasma as an aid in the diagnosis of patients with congestive heart failure. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the act, the Biosite Diagnostics BNP test system is subject to a special control guidance document entitled ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.''

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, the device is not exempt from the premarket notification requirements. The test is used in the diagnosis of patients with congestive heart failure. FDA review of data sets and labeling ensure that minimum levels of performance are obtained before marketing and are subject to impartial external quality control before labeling is put into place. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the BNP test system before marketing the device.

On November 20, 2000, FDA issued an order to the petitioner classifying the Biosite Diagnostics BNP test system, and substantially equivalent devices of this generic type, into class II under the generic name, BNP test system. FDA identifies this generic type of device as a BNP test system, which is intended to aid in the diagnosis of congestive heart failure. FDA is codifying this device by adding § 862.1117. This order also identifies a special control applicable to this device ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.''

II. Electronic Access

In order to receive the draft guidance entitled ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers'' via your fax machine, call the CDRH Facts on Demand System at 800–899–0381 or 301–827–0111 from a touch-tone

telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1183) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notification; Final Guidance for Industry and FDA Reviewers'' is available at http://www.fda.gov/cdrh/ode/guidance/1072.pdf.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–1210), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA knows of only one manufacturer of this type of device. Classification of these devices in class II will relieve this manufacturer of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e) and may permit small potential competitors to enter the market place by lowering their costs. The agency, therefore, certifies that this 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 of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

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

2. Section 862.1117 is added to subpart B to read as follows:

§ 862.1117 B-type natriuretic peptide test system.

(a) *Identification.* The B-type natriuretic peptide (BNP) test system is an in vitro diagnostic device intended to measure BNP in whole blood and plasma. Measurements of BNP are used as an aid in the diagnosis of patients with congestive heart failure.

(b) *Classification.* Class II (special controls). The special control is ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.''

Dated: January 11, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–4847 Filed 2–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 97P–0354]

Medical Devices; Reclassification of the Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint from class III to class II (special controls). The agency is also announcing that it has issued an order in the form of a letter to the Orthopedic Surgical Manufacturers Association (OSMA) reclassifying the device. The special control that will apply is a guidance document entitled ''Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis.'' The agency is classifying this device into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls.