Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

User assistance is available for RIMS, CIPS, and the Website during normal business hours from our Help line at (202) 208–2222 (E-Mail to *WebMaster@ferc.fed.us*) or the Public Reference at (202) 208–1371 (E-Mail to *public.referenceroom@ferc.fed.us*).

During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Website are available. User assistance is also available.

List of Subjects in 18 CFR Part 157

Administrative practice and procedure, Natural gas, Reporting and recordkeeping requirements.

By the Commission.

David P. Boergers,

Secretary.

In consideration of the foregoing, the Commission amends Part 157, Chapter I, Title 18, *Code of Federal Regulations,* as follows.

PART 157—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY AND FOR ORDERS PERMITTING AND APPROVING ABANDONMENT UNDER SECTION 7 OF THE NATURAL GAS ACT

1. The authority for Part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

2. In § 157.202, the introductory text in paragraph (b)(6) is revised to read as follows:

§ 157.202 Definitions.

* * * * *

(b) * * *

(6) *Miscellaneous rearrangement* of any facility means any rearrangement of a facility, excluding underground storage injection/withdrawal wells, that does not result in any change of service rendered by means of the facilities involved, including changes in existing field operations or relocation of existing facilities:

* * * * *

§ 157.211 [Amended]

3. In § 157.211(c) the reference to ''(a)(1)'' is removed and a reference to ''(a)'' is added in its place.

[FR Doc. 00–5116 Filed 3–2–00; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 96P–0436]

Medical Devices; Anesthesiology Devices; Classification of Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nitric oxide administration apparatus, nitric oxide analyzer, and nitrogen dioxide analyzer into class II (special controls). The special control that will apply to these devices is a guidance document. 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 amendments), 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 devices.

DATES: This rule is effective April 3, 2000.

FOR FURTHER INFORMATION CONTACT: Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 164.

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 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 class 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.

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 January 6, 2000, classifying the device 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 which was subsequently reclassified into class I or class II. On January 7, 2000, Datex-Ohmeda submitted a petition requesting classification of the nitric oxide administration apparatus, nitric oxide analyzer, and nitrogen dioxide analyzer under section 513(f)(2) of the act. This petition incorporated by reference a reclassification petition that Datex-Ohmeda had submitted previously. The manufacturer recommended that the device be classified into class II.

After review of the information submitted in the original reclassification petition, the premarket notification submission (K974562), the panel recommendation of November 22, 1996, on the original reclassification petition, the automatic evaluation of class III designation petition, and the information developed by FDA to address concerns about delivery and monitoring of this drug, FDA determined that the INOvent Delivery System intended for use in administering nitric oxide, measuring nitric oxide, and measuring nitrogen dioxide can be classified in class II with

the establishment of special controls. FDA believes that class II special controls, in addition to the general controls, provide reasonable assurance of the safety and effectiveness of the device.

The delivery system consists of three devices to which FDA assigns the generic names ''nitric oxide administration apparatus,'' ''nitric oxide analyzer,'' and ''nitrogen dioxide analyzer.'' The devices are identified as follows:

1. Nitric oxide administration apparatus is a device used to add nitric oxide to gases that are to be breathed by a patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system.

2. Nitric oxide analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.

3. Nitrogen dioxide analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.

On January 11, 2000, FDA issued an order to the petitioner classifying the nitric oxide administration apparatus, nitric oxide analyzer, and nitrogen dioxide analyzer described previously into class II subject to the special controls described below. Additionally, FDA is codifying the classification of these devices by adding §§ 868.2380, 868.2385, and 868.5165. In addition to the general controls of the act, the special control developed by the agency is a guidance document entitled ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.'' This guidance document identifies the risks associated with these types of devices and contains information that will help manufacturers address those risks. This document is available on the Internet at http://www.fda.gov/cdrh/ode/1157.pdf.

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 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 104–121)), 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 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. Reclassification of these devices 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 act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections 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 868

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 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

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

2. Section 868.2380 is added to subpart C to read as follows:

§ 868.2380 Nitric oxide analyzer.

(a) *Identification*. The nitric oxide analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.

(b) *Classification*. Class II. The special control for this device is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.''

3. Section 868.2385 is added to subpart C to read as follows:

§ 868.2385 Nitrogen dioxide analyzer.

(a) *Identification*. The nitrogen dioxide analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.

(b) *Classification*. Class II. The special control for this device is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.''

4. Section 868.5165 is added to subpart F to read as follows:

§ 868.5165 Nitric oxide administration apparatus.

(a) *Identification*. The nitric oxide administration apparatus is a device used to add nitric oxide to gases that are to be breathed by a patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system.

(b) *Classification*. Class II. The special control for this device is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.''

Dated: February 24, 2000.

Linda S. Kahan,

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

[FR Doc. 00–5160 Filed 3–2–00; 8:45 am]

BILLING CODE 4160–01–F