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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5297]

Medical Devices; Guidance Document for Premarket Notification Submissions for the Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance Document for Premarket Notification Submissions for the Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer." This guidance will serve as a special control for nitric oxide delivery apparatus; nitric oxide analyzer; and nitrogen dioxide analyzer. FDA's Center for Devices and Radiological Health (CDRH) believes that this guidance is necessary to provide reasonable assurance of the safety and effectiveness of these devices. The guidance document includes material specific for the devices, consensus standards for electrical safety, electromagnetic compatibility, software and hardware documentation, and resistance to environmental effects.

DATES: Written comments concerning this guidance document must be received by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document. Submit written requests for single copies of the guidance document entitled "Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug

Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. By [*insert date 90 days after date of publication*], written comments concerning this guidance document must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. After [*insert date 90 days after date of publication*], comments must be submitted to the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Michael G. Bazaral, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609.

SUPPLEMENTARY INFORMATION:

I. Background

On January 11, 2000, FDA issued an order to Datex-Ohmeda, Inc., under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) classifying the nitric oxide administration apparatus, the nitric oxide gas analyzer, and the nitric dioxide analyzer into class II (special controls). This guidance document is intended to serve as the special control for these devices.

FDA is making this guidance document effective immediately because these devices are necessary for the administration of a drug that provides a significant public health benefit. The drug, which was approved by FDA on December 23, 1999, is used for the treatment of neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The drug improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

The guidance document is intended to set forth the controls and testing that FDA believes ensure the safety and effectiveness of the nitric oxide administration apparatus, nitric oxide gas analyzer, and nitrogen dioxide gas analyzer. It also intends to provide comprehensive directions

to enable a manufacturer to submit a 510(k) premarket notification demonstrating substantial equivalence for any or all three device types.

The guidance document identifies the risks associated with these types of devices and contains information that will help manufacturers address those risks. The guidance outlines the controls that should be incorporated in the devices for controlling risks, testing that should be completed for each device, and suggested methods for developing preclinical criteria. Other elements of the guidance document include: (1) General device description; (2) specific description of the information to support applications for each device; and (3) general considerations for each device, such as software and hardware testing.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the premarket notification submissions for the nitric oxide delivery apparatus, nitric oxide analyzer, and nitrogen dioxide analyzer. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

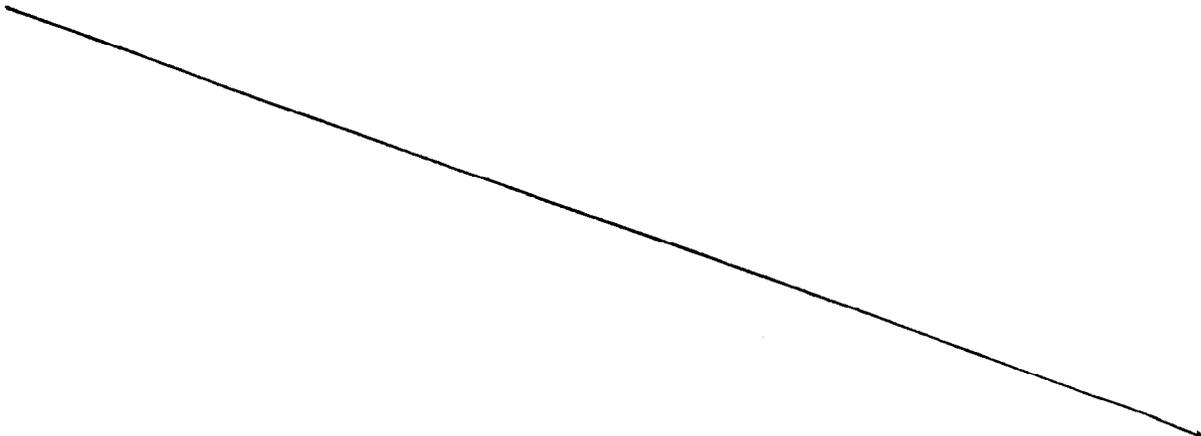
In order to receive the "Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice

prompt press 2, and then enter the document number (1157) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document 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. Updated on a regular basis, the CDRH home page includes the “Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer,” device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The “Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer” will be available at <http://www.fda.gov/cdrh/ggpmain.html>.

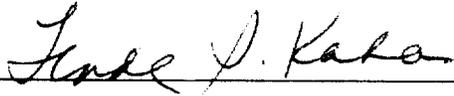
IV. Comments

Interested persons may, on or before [*insert date 90 days after date of publication in the Federal Register*], submit to the Dockets Management Branch (address above) written comments regarding this immediately in effect guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified



with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/13/00
January 13, 2000



Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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