Guidance for Industry and for FDA Reviewers

Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Anesthesiology, Respiratory, and Defibrillator Devices Group
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to Docket No. 99D-5297, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, (HFA-305), Room 1061, Rockville, MD 20852.. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance comments and suggestions may be submitted at any time for Agency consideration to: Michael Bazaral, M.D., Ph.D., Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Michael Bazaral, M.D., Ph.D. at 301-443-8609.

Additional Copies

World Wide Web/CDRH/home page at http://www.fda.gov/cdrh/ode/1157.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1157 when prompted for the document shelf number.

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