



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (jsh)
FOLDER: K120216 - 2607 pages
COMPANY: GENO LLC (GENOC)
PRODUCT: APPARATUS, NITRIC OXIDE DELIVERY (MRN)
SUMMARY: Product: GENOSYL MV-1000

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510(k) Summary

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Proprietary or Trade Name: GeNOsyl™ MV-1000

Classification / CFR / Classification Name:

Product Code	CFR	Classification name
MRN	868.5165	Nitric oxide administration apparatus, primary delivery system
MRO	868.6165	Nitric oxide administration apparatus, backup delivery system
MRP	868.2380	Nitric oxide gas analyzer
MRQ	868.2385	Nitrogen dioxide gas analyzer

Class: All are Class 2

Predicate Devices: Ikaria INOmax DS – K061901

Device Description:

GeNOsyl MV-1000 Delivery System includes four components:

1. Nitric oxide administration apparatus, primary delivery system
2. Nitric oxide gas analyzer
3. Nitrogen dioxide gas analyzer
4. Nitric oxide administration apparatus, backup delivery system

The nitric oxide administration apparatus adds nitric oxide to gases that are to be inhaled by the patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system. The concentration of nitric oxide is maintained approximately constant during the inspiratory flow regardless of the variation in flow rate within the inspiratory portion of the respiratory cycle. The concentration of inspired nitric oxide will or must be set by the user, typically in the range of 0 to 80 parts per million (ppm).

The administration apparatus includes a pressure regulator and connectors with fittings which are specific for nitric oxide gas cylinders, containing 800 ppm nitric oxide in nitrogen. The nitric oxide delivery apparatus shall minimize the time that nitric oxide is mixed with oxygen and thus minimize the concentration of nitrogen dioxide in the gas inhaled by the patient. In the presence of O₂, some conversion of nitric oxide to nitrogen dioxide will occur. The GeNOsyl™ administration apparatus includes a cartridge which will serve a dual purpose: a mixing chamber and to convert any transient nitrogen dioxide to nitric oxide prior to inhalation by the patient.

