K021742

OCT 25 2002

12. GaleMed Neb-Easy Nebulizer 510(k) Summary:

In accordance with 21 CFR section 807.92 GaleMed is submitting the following safety and effectiveness summary.

1) Submitter Information

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2) Name of Device

Proprietary Name: Neb-Easy Nebulizer
Common Name is Nebulizer
Classification Name: Nebulizer

3) Substantially equivalent to: Allegiance Misty-Neb Nebulizer (K883968).

4) Device Description and System Overview:

General Description of the Device:

The nebulizer is a device intended to spray liquids in aerosol form into gasses that are delivered directly to the patient for breathing. It is a Class II device, regulation number: 868.5630.

This device operates on the venturi principle and is refillable. The device is called the GaleMed Neb-Easy Nebulizer. It is made from acrylic and polypropylene plastics, is injection molded and is intended for single patient use for up to 28 days. These material types are used in other predicate devices, such as the Salter Labs and Allegiance Airlife product lines. The specific materials have been tested for biocompatibility to ISO 10993 and results showed them to be non-reactive. All testing requirements contained in the "Reviewer Guidance: Nebulizers, Metered Dose Inhalers, Spacers and Actuators, 10/01/93" have been completed and were submitted by GaleMed for FDA review in their premarket notification submission. Comparative testing data to the predicate device (Allegiance Airlife Misty-Neb, K883964) was also performed at a third party independent test laboratory to the requirements of the "Reviewers Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators, 10/01/93."

The Neb-Easy Nebulizer has several attachments that are used with it during the nebulization process. These include a Tee Connector, which connects to the top of the nebulizer; a mouthpiece and a 6 inch corrugated tube, which connects to the side of the Tee connector opposite the

opposite the mouthpiece. These are standard accessories to class 1 oxygen masks and breathing circuits as well as being considered standard accessories to a nebulizer devices.

Table 1a: List of Accessories and Regulatory Status.

Accessory	Part #	Manufacturer	Regulatory Status
Mouth Piece	3394-B	GaleMed Corp.	Class 1 device exempt from pre-market notification
Tee Connector	TZ-3393	GaleMed Corp.	Class 1 device exempt from pre-market notification
6" Corrugated Tubing	740-01	GaleMed Corp.	Class 1 device exempt from pre-market notification
Oxygen Supply Tubing	34502-YY	GaleMed Corp.	Class 1 device exempt from pre-market notification

A standard oxygen tube connects to the bottom of the Neb-Easy Nebulizer and serves to connect the nebulizer to a pressurized gas source. This gas source is used to create the venturi and high flow conditions inside of the Neb-Easy that are used to create respirable aerosols. Flow rates are determined by the physician, but are typically between 5 lpm and 9 lpm.

The accessories, attachments, principles of operation and materials are all essentially equivalent to predicate devices already cleared by FDA.

The GaleMed Design System

GaleMed has in place a fully operational quality system that conforms to ISO 9001:1994, EN 46001:1996, the QSR and required elements of the Medical Device Directive. All new products are processed according to the requirements of 21 CFR Part 820.30. Design History Files are maintained for all new development projects and the products are tested in the United States by MDVentures prior to the submission process.

Table 1: Comparison of Neb-Easy Materials to predicate Allegiance Misty Neb Nebulizer

Nebulizer Component:	GaleMed Neb-Easy Nebulizer	Allegiance MistyNeb (883964)
Cup: material and GaleMed component material specification #:	Acrylic, Cyro 20G-Hiflow part #001-0129-01 (equivalent to polystyrene)	Polystyrene, supplier unknown
Top Cap: material and GaleMed component material specification #:	Polypropylene, Basell Profax 549M or Fina 7235, GaleMed part #001-0126-01	Polystyrene, supplier unknown
Cone Insert: material and GaleMed component material specification #:	Acrylic, Cyro 20G-Hiflow, GaleMed part #001-0128-01	Polystyrene, supplier unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2002

GaleMed Corporation
C/O Mr. Thomas Shanks
MDVentures
29201 Via Norte
Temecula, California 92591

Re: K021742
Trade Name: Gale-Med Neb-Easy Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: 73 CAF
Dated: September 4, 2002
Received: September 10, 2002

Dear Mr. Shanks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

Timothy A. Ulatowski
Director
Division of Anesthesiology,
General Hospital, Infection Control
and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use

510(k) Number: K021742

Device Name: Neb-Easy Nebulizer

Indications for Use:

The GaleMed Neb-Easy Nebulizer is a pneumatic nebulizer which nebulizes specific drugs for inhalation by a patient. It is for adult and pediatric patients.

X Prescription use -or- ___ Over-the-counter use

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K021742