K093584

510(k) Summary

MAR - 4 2011

General Information

Owner's Name:	N.M. Beale Co., Inc.
Address:	P.O. Box 494 Harvard, MA 01451
Telephone Number:	(800) 989-9558
Contact Person:	Nathaniel Beale, President
Date Prepared:	September 13, 2010

Subject Device:

Trade Name:	EZ-Mister
Classification/Regulation:	CCT – Applicator, laryngo-tracheal, topical anesthesia 21 CFR 868.5170; Class II

Predicate Devices:

Trade Name:	Laryngeal Atomizer (Sharn, Inc);
Classification/Regulation:	CCT – Applicator, laryngo-tracheal, topical anesthesia 21 CFR 868.5170; Class II
Premarket Notification:	K070596

Device Description

The EZ-Mister consists of a plastic atomizer used to deliver topical anesthetic solutions. The device includes a receptacle intended to contain a single container of topical anesthetic; the atomizer housing has a plastic tube that extends into the anesthetic solution. The device uses oxygen flow to achieve atomization.

Indications for Use

The EZ-Mister is indicated for use in atomizing topical anesthetics to the oropharynx and upper airway regions.

Performance Testing

Performance data provided in this submission consists of particle size testing.

Substantial Equivalence

The EZ-Mister is substantially equivalent to the currently marketed Sharn Inc. Laryngeal Atomizer, which was cleared for marketing in K070596, and which has the same indications for use as the EZ-Mister. The essential technological characteristics of the proposed and predicate devices are the same – both are disposable atomizers intended for use to deliver topical anesthetics via atomization achieved via pressurized gas flow. The predicate Sharn Laryngeal Atomizer consists of a plastic tube with an atomizer tip and a 3 mL piston syringe. The topical anesthetic is drawn up into the syringe; the user then depresses the syringe plunger to deliver the

atomized anesthetic to the desired location in the patient's oropharynx / upper airway. The EZ-Mister described in this submission does not incorporate a syringe. To achieve atomization, the EZ-Mister is attached to an oxygen source that has been set to a specified flow rate; gas flow through the atomizer mechanism draws the anesthetic up through the tube where it is mixed with the gas to create a mist. The user can control the flow of anesthetic for both the E-Z Mister and the Sharn Laryngeal Atomizer.

Conclusion

The EZ-Mister is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

N.M. Beale Company, Incorporated
C/O Ms. Pamela Papineau
Regulatory Affairs Consultant
Delphi Medical Device Consulting, Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

MAR - 4 2011

Re: K093584
Trade/Device Name: EZ-Mister
Regulation Number: 21 CFR 868.5170
Regulation Name: Laryngotracheal Topical Anesthesia Applicator
Regulatory Class: II
Product Code: CCT
Dated: February 25, 2011
Received: March 1, 2011

Dear Ms. Papineau:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K093584

Device Name: EZ-Mister

Indications for Use:

The EZ-Mister is indicated for use in atomizing topical anesthetics to the oropharynx and upper airway regions.

Prescription Use __X___ OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

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

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