Non-Confidential Summary of Safety and Effectiveness

25-May-07

JUN 2 1 2007

Sharn, Inc.
4517 George Rd. # 200 Tel – 813-889-9614
Tampa, FL 33634 Fax – 813-886-2701

Official Contact: Bruce Tomlinson - President

Proprietary or Trade Name: Topical applicator

Common/Usual Name: Atomizer

Classification Name: Laryngo-Tracheal topical applicator

Classification Code: CCT – 21 CFR 868.5170

Device: Topical Applicator

Predicate Devices: Wolfe Tory – MADgic - K002255
Sherwood Monoject syringe – K852544

Device Description: The Topical applicator incorporates a small tube with atomizing tip which can connect to a syringe and when placed in the patient's mouth or throat and / or inside an endotracheal tube or in the nasal passages it then delivers topical anesthetic solutions.

Indications for Use: Intended for atomizing topical anesthetics to the oropharynx and upper airway regions

Environment of Use: Hospitals, sub-acute settings where topical solutions are needed.

Patient Population: Individuals requiring topical anesthetic at the direction and discretion of the clinician.

Differences Between Other Legally Marketed Predicate Devices

The Sharn Topical Applicator when compared in performance testing for particle size and plume geometry to the predicate, Wolfe Tory MADgic – K002255 was found to be substantially equivalent.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

Non-Confidential Summary of Safety and Effectiveness

25-May-07

Features	Predicate Wolfe Tory MADgic K002255	Proposed Device
Indications for use	Intended for the application of topical anesthetics to the oropharynx and upper airway region	Intended for the application of topical anesthetics to the oropharynx and upper airway region
Types of medications used	Topical solutions, i.e., Topical anesthetics Vasoconstrictors	Topical solutions, i.e., Topical anesthetics Vasoconstrictors
Environment of Use / Patient population	Not disclosed	Locations where topical anesthetics solutions are used. Individuals requiring topical anesthetic at the direction and discretion of the clinician.
Disposable, non-sterile	Yes	Yes
Components	Syringe Flexible, malleable, semi-rigid tube Atomizer tip / nozzle	Syringe (k852544) Flexible, semi-rigid tube Atomizer tip / nozzle
Places inserted	Nasal, Orotrachael	Nasal. Orotrachael
Dosage Amount	User controlled	User controlled
Delivery form	Fine particle spray mist	Fine particle spray mist
Spray generated by	Piston syringe	Piston syringe
Basic dimensions	Tip diameter – 0.157" OD Tube length – 8.25" overall	Tip diameter – 0.31" OD (7.9 mm) Tube length – 8.25" overall
Materials	Polycarbonate Polyvinylchloride (PVC)	Acetal/ Delrin, K-resin Polyethylene, Polyvinylchloride
Biocompatibility	Unknown	Tested to ISO 10993-1
Performance testing	Comparative using Cascade impactor to measure the following listed criteria	
Total Dose Delivered max 3 cc	2.88 cc – Lidocaine 2.87 cc – Saline	2.75 cc - Lidocaine 2.78 cc - Saline
Residual Mass (cc) Ave.	0.12 cc	0.25 cc
Simulated Clinical Dose %	94.7% – Lidocaine 95.0% – Saline	92.3% - Lidocaine 94.0% - Saline
Particle Size MMAD (um)	470 um – Lidocaine 470 um – Saline	835 um - Lidocaine 803 um - Saline
GSD (um)	1.87 um – Lidocaine 1.90 um – Saline	1.93 um - Lidocaine 2.00 um - Saline
Plume Geometry Evaluated using digital image and photographic grid measuring spray distance, velocity, dispersion angle all vs. time	Similar	Similar

Discussion and Table of the Comparison and Differences

Features	Predicate Wolfe Tory MADgic K002255	Proposed Device
Indications for use	Intended for the application of topical anesthetics to the oropharynx and upper airway region	Intended for the application of topical anesthetics to the oropharynx and upper airway region
Types of medications used	Topical solutions, i.e., Topical anesthetics, Vasoconstrictors	Topical solutions, i.e., Topical anesthetics Vasoconstrictors
Environment of Use / Patient population	Not disclosed	Locations where topical anesthetics solutions are used. Individuals requiring topical anesthetic at the direction and discretion of the clinician.
Disposable, non-sterile	Yes	Yes
Components	Syringe Flexible, malleable, semi-rigid tube Atomizer tip / nozzle	Syringe (k852544) Flexible, semi-rigid tube Atomizer tip / nozzle
Places inserted	Nasal, Orotrachael	Nasal, Orotrachael
Dosage Amount	User controlled	User controlled
Delivery form	Fine particle spray mist	Fine particle spray mist
Spray generated by	Piston syringe	Piston syringe
Device dead space (ml)	0.12 ml device only	0.13 ml device only
Basic dimensions	Tip diameter – 0.157" OD Tube length – 8.25" overall	Tip diameter – 0.31" OD (7.9 mm) Tube length – 8.25" overall
Materials	Polycarbonate Polyvinylchloride (PVC)	Acetal / Delrin, K-resin Polyethylene Polyvinylchloride (PVC)
Biocompatibility	Unknown	Tested to ISO 10993-1
Performance testing	Comparative using Cascade impactor to measure the following listed criteria	
Total Dose Delivered max 3 cc	2.88 cc – Lidocaine 2.87 cc – Saline	2.75 cc - Lidocaine 2.78 cc - Saline
Residual Mass (cc) Ave.	0.12 cc	0.25 cc
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GSD (um)	1.87 um – Lidocaine 1.90 um – Saline	1.93 um - Lidocaine 2.00 um - Saline
Plume Geometry Evaluated using digital image and photographic grid measuring spray distance, velocity, dispersion angle all vs. time	Similar see Section 18	Similar see Section 18

Discussion:

Particle Size:

While the difference represents a measurable difference, it would not be classified as "substantially different." The intent of the device is to deliver a topical medication to a specific sight in close proximity to the tip. Therefore bigger particles are important, otherwise the medication may be inhaled to another location that is not intended (alveolar). Both particle sizes of the respective devices are sufficiently large to insure this.

The simulated clinical dose for both devices were equal, and almost exactly equal to the "filled dose" minus the "residual", is further verification of this position (i.e., all medication was accounted for at the sight of delivery or remaining in the device, none was inhaled).

Therefore both devices equally performed their function and are "substantially equivalent."

Tube malleable wire:

The proposed device does not include a malleable wire in the tubing as this is a patented feature. We believe that the intent of the malleable wire was to allow the tube to hold a curve or shape for insertion into the patient's throat. However this feature is not a requirement for any atomizer to be functional.

The lack of a malleable wire does not introduce or create any new safety or performance issues in fact one might consider our design as "safer" as the tube is less stiff. This is not a claim which is proposed to be used or demonstrated.

The use of K-resin for our tubing allows the clinician to bend the tube and for it to "hold" some curve or shape, anatomical, during the intended use.

Therefore there are no significant differences between the proposed device and the predicate.

It is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sharn, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court # 102
Bonita Springs, Florida 34134-2015

JUN 21 2007

Re: K070596
Trade/Device Name: Topical Applicator
Regulation Number: 21 CFR 868.5170
Regulation Name: Laryngotracheal Topical Anesthesia Applicator
Regulatory Class: II
Product Code: CCT
Dated: June 11, 2007
Received: June 12, 2007

Dear Mr. Dryden:

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K070596

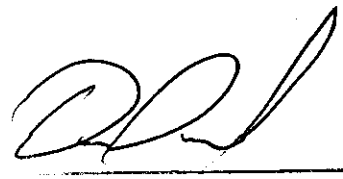
Device Name: Topical applicator

Indications for Use: Intended for atomizing topical anesthetics to the oropharynx and upper airway regions

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number: K070596