SEP 1 1 2002

510(K) Summary: K021044
Summary of Safety and Effectiveness

Company and Submission Information

Applicant	Tim Wolfe, MD – Medical Director Wolfe Tory Medical, Inc. 79 West 4500 South, Suite 16 Salt Lake City, UT 84107 (801) 281-3000
Contact	Tim Wolfe, MD
Date Prepared	March 26, 2002, Revised – June 25, 2002
Establishment Registration Number	1722554
Classification Name and Product Code	Accessory, Endotracheal tube 73 BTR
Classification	Class II
Panel	Anesthesiology
Common/Usual Name	Atomizer
Trade Name	MADett
Predicate Devices	Stat-Med® Manufactured by Sheridan (Patented by Sheridan Catheter Corporation in 1971; Also called LITA) Preamendment: No 510K due to use prior to May 1976. EMT® Emergency Medicine Tube Manufactured by Mallinckrodt Medical 510(k)# K802505 approved March 13, 1981 MedPort™ Emergency Medication Airway Tube Adapter Manufactured by Greenfield Medical Products 510(k)# K971759 approved March 2, 1998
Performance Standards	None established

Device description:

The Endotracheal Mucosal Atomization Device (MADett) is a disposable, sterile device that converts a topical solution into a fine particle spray for application into the trachea beyond the ETT. The clinician connects the device in line between the endotracheal tube and the ventilation device. The clinician then attaches a syringe of topical medication to the luer lock fitting of the atomizer and delivers medications into the trachea while simultaneously ventilating the patient.

Indications For Use:

1. To establish a path in which to inject medication into the lungs of a patient who is being ventilated through an intubated airway.

2. To establish a means in which to introduce medication into an intubated airway without interrupting the flow of life-supporting ventilation to the patient.

Predicate devices:

1. Stat-Med® manufactured by Sheridan (Patented by Sheridan Catheter Corporation in 1971; Also called LITA) – Preamendment device: No 510K due to use prior to May 1976.
2. EMT® Emergency Medicine Tube manufactured by Mallinckrodt Medical; 510(k)# K802505 approved March 13, 1981.
3. MedPort™ Emergency Medication Airway Tube Adapter manufactured by Greenfield Medical Products; 510(k)# K971759 approved March 2, 1998

Table Comparing the MADett to Predicate Devices

	Endotracheal Mucosal Atomization Device: Wolfe Tory	Stat-Med® - Kendall EMT - Mallinckrodt	MedPort™ - Greenfield Medical
Indications for use	To apply medications through an endotracheal tube in an effective manner while reducing risk of splash back onto the clinician. ET Tube not included as part of the device.	To apply medications through an endotracheal tube in an effective manner while reducing risk of splash back onto the clinician. The ET tube is part of the overall device.	To apply medications through an endotracheal tube in an effective manner while reducing risk of splash back onto the clinician. ET Tube not included as part of the device.
Medication and Dosage amount	User controlled	User controlled	User controlled
Target population	Intubated patients requiring pulmonary fluid or medication administration as determined by the treating physician.	Intubated patients requiring pulmonary fluid or medication administration as determined by the treating physician.	Intubated patients requiring pulmonary fluid or medication administration as determined by the treating physician.
Delivery form	Fine particle spray mist	Droplet particle spray mist	Droplet particle spray mist
Cannula length	20 inches – length of insertion into ETT varies based on size of ETT.	Length of ETT – varies depending on tube size.	No cannula – connects to proximal tube.
Cannula shape	Semi-rigid	Semi-rigid	No cannula
Power source - Spray generated by	Piston syringe	Piston syringe	Piston syringe
Materials	Polycarbonate and polyvinyl chloride	Polypropylene and polyvinyl chloride	"Medical plastic"
Skill level required	Similar	Similar	Similar
Injection port	Luer lock compatible	Luer lock compatible	Luer lock compatible
Sizes	Fits 7.0 to 9.0 ETT	Comes with 6.0 to 8.5 ETT	Fits "full range of airway tube sizes"
Disposable	Yes	Yes	Yes

Discussion of Substantial Equivalency to predicate devices:

The Wolfe Tory MADett fulfills the requirements set down by the FDA for substantial equivalency to several currently marked devices for the following reasons:

1. All four devices are designed for the same intended use:

- To establish a path in which to inject medication into the lungs of a patient who is being ventilated through an intubated airway.

- To establish a means in which to introduce medication into an intubated airway without interrupting the flow of life-supporting ventilation to the patient.

2. Though minimally technologically different from the predicate devices, the MADett meets criteria set down by the FDA to allow substantial equivalency:

The MADett technical design is very similar to the predicate devices and the principles of operation and indications for use are identical. The major difference is that the predicate devices medication lumen is embedded into the ETT wall and is part of the ETT itself, whereas the MADett is a separate device from the ETT and the MADett lumen is positioned within the ETT rather than embedded in its side wall. This minimal difference does not raise questions regarding safety and effectiveness. Furthermore, the MADett is made up of similar materials as the predicate devices. These parts and their design have performance testing data and biocompatibility data provided in this 510k and its addendum's proving they are safe for their intended use. Their combination into the current design creates a device nearly identical to already approved and marketed predicate devices and offers no new questions regarding safety and effectiveness.

Conclusions

The MADett device described in this 510K is very similar in terms of design, materials and indications for use to three predicate devices already approved and marketed. There are no new safety concerns when compared to the already available predicate devices. For these reasons, we feel the MADett fulfills all criteria to be found substantially equivalent to the predicate devices and should be cleared for marketing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Tim Wolfe, M.D.
Medical Director
Wolfe Tory Medical, Incorporated
79 West 4500 South, Suite 16
Salt Lake City, Utah 84107

Re: K021044
Trade/Device Name: Endotracheal Mucosal Atomization Device (MADett)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: II
Product Code: BTR
Dated: July 3, 2002
Received: July 9, 2002

Dear Dr. Wolfe:

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

Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: Wolfe Tory Medical, Inc.

510(k) Number (if known): K021044

Device Name: Endotracheal Mucosal Atomization Device (MADett)

Indications For Use:

1. To establish a path in which to inject medication into the lungs of a patient who is being ventilated through an intubated airway.

2. To establish a means in which to introduce medication into an intubated airway without interrupting the flow of life-supporting ventilation to the patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the –counter use ____
(Optional Format 1-2-96)

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

510(k) Number: K021044