510(K) Summary
Summary of Safety and Effectiveness

Company and Submission Information

| Applicant                          | Wolfe Tory Medical, Inc.  
|                                  | 79 West 4500 South, Suite 21  
|                                  | Salt Lake City, UT  84107  
|                                  | (801) 281-3000  
| Contact                          | Tim Wolfe, MD  
| Date Prepared                    | 7/21/00  
| Classification Name              | Applicator, laryngo-tracheal, topical anesthesia  
|                                  | 73 CCT  
| Common/Usual Name                | Atomizer  
| Proprietary Name and            | Laryngo-Tracheal Mucosal Atomization Device (MADgic™)  
| Legally Marketed Device          |  
| Device Description               | Disposable non-sterile device designed for atomizing topical  
|                                  | solutions across the nasal and oropharyngeal mucous membranes.  
| Substantial Equivalence          | Astra Disposable Spray Cannula  
|                                  | K894755  

Comparison to Predicate Device

<table>
<thead>
<tr>
<th>WT Laryngo-Tracheal Mucosal Atomization Device</th>
<th>Astra Disposable Spray Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage amount</td>
<td>User controlled</td>
</tr>
</tbody>
</table>
|                                               | Dependent on pump, metered dosage.  
| Delivery form                                  | Fine particle spray mist        |
|                                               | Fine particle spray mist        |
| Cannula shape                                  | Semi-rigid                      |
|                                               | Semi-rigid                      |
| Spray generated by                             | Piston syringe                  |
|                                               | Pressurized container           |
| Spray tip diameter                             | 0.157"                         |
|                                               | 0.316”                         |
| Materials                                      | Polycarbonate and               |
|                                               | polyvinylchloride               |
|                                               | Polypropylene                   |
| Disposable                                     | Yes                             |
|                                               | Yes                             |

Summary of Research Findings

Endotracheal tube placement elicits numerous physiologic responses in the human organism. These include significant sympathoadrenal responses such as hypertension, tachycardia, elevation of intracranial pressure, increase in intraocular pressure and increase in circulating catecholamines (epinephrine and norepinephrine)[8, 10-18]. In non-pharmacologically paralyzed patients multiple reflex responses also occur including the gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-9]. In most situations, these responses do not lead to serious adverse patient outcomes. However, in a substantial number of cases these responses would be best avoided. The solution to these problems is the application of topical anesthetics to the oropharynx and upper airway. An extensive body of literature exists.
that demonstrates topical anesthetics attenuate the sympathetic response to intubation while simultaneously reducing or eliminating problems with gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-18]. These topical anesthetics are typically applied with laryngotracheal applicator type devices. Wolfe Tory Medical wishes to introduce a new laryngo-racheal applicator called the Laryngo-Tracheal Mucosal Atomization Device.

Conclusions

The process of intubation of the trachea leads to several physiologic and reflex responses by the human body[1]. Application of topical anesthetics to the oropharynx and upper airway prior to intubation results in substantial attenuation of these adverse responses[2-18]. The Laryngo-Tracheal Mucosal Atomization Device safely, gently and effectively applies topical anesthetics to mucosal surfaces. Use of the Laryngo-Tracheal Mucosal Atomization Device to apply anesthetic to the upper airway will attenuate or eliminate these adverse physiologic and reflex responses leading to improved patient outcomes.

References:

SEP 1 8 2000

Mr. Tim Wolfe
Wolfe Tory Medical, Inc.
79 West 4500 South, Suite 21
Salt Lake City, UT 84107

Re: K002255
Laryngo-Tracheal Mucosal Atomization Device (Madgic)
Regulatory Class: II (two)
Product Code: 73 CCT
Dated: July 21, 2000
Received: July 25, 2000

Dear Mr. Wolfe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 yours,

James E. Dillard III
Director
Division of Cardiovascular and Respiratory 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): K002255

Device Name: Laryngo-tracheal Mucosal Atomization Device (MADgic™)

Indications For Use:

Intended for the application of topical anesthetics to the oropharynx and upper airway region.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Memorandum

Date: 9/20/00

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K002955-12

To: Division Director: AN/OCR D

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

Additional information requires a new 510(k); please process [This information will be made into a new 510(k)]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement)

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: William A. Not

Date: 9/25/00

Draft #2: 9/8/99
Draft #3: 1/3/00
September 14, 2000

Mr. William Noe
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Dear Mr. Noe,

I have provided below the additional information that you requested for our 510 (k) submission number K002255:

(b) (4)

Please let me know if there is any additional information that you may require.

Sincerely,

[Signature]
Marshall T. Denton
VP and General Manager
Mr. Tim Wolfe  
Wolfe Tory Medical, Inc.  
79 West 4500 South, Suite 21  
Salt Lake City, UT 84107  

Re: K002255  
Laryngo-Tracheal Mucosal Atomization Device (Madgic)  
Regulatory Class: II (two)  
Product Code: 73 CCT  
Dated: July 21, 2000  
Received: July 25, 2000  

Dear Mr. Wolfe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

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Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and Respiratory 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): K002255

Device Name: Laryngo-tracheal Mucosal Atomization Device (MADgic™)

Indications For Use:

Intended for the application of topical anesthetics to the oropharynx and upper airway region.

X Prescription Use or __ Over-The-Counter Use

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)
From: Reviewer(s) - Name(s)  
William A. Noe

Subject: 510(k) Number- (CC 2255)

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? □ YES □ NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? □ YES □ NO

Is this device subject to the Tracking Regulation? □ YES □ NO

Was clinical data necessary to support the review of this 510(k)? □ YES □ NO

Is this a prescription device? □ YES □ NO

Was this 510(k) reviewed by a Third Party? □ YES □ NO

Special 510(k)? □ YES □ NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers □ YES □ NO

This 510(k) contains:

- Truthful and Accurate Statement □ Requested □ Enclosed
  (required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin □ YES □ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality □ Confidentiality for 90 days □ Continued Confidentiality exceeding 90 days

**Topical Anesthetic Applicator (Larynx - Trachea)**

Predicate Product Code with class: 73 CCT (II)

Additional Product Code(s) with panel (optional):

Review:

Branch Chief

Date: 7/18/00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)

New Device is Compared to Marketed Device

Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (In Deciding, May Consider Impact on Safety and Effectiveness)?

Yes

New Device Has New Intended Use

No

Yes

"Not Substantially Equivalent" Determination

Does New Device Have Same Indication Statements?

Yes

New Device Has Same Intended Use and May Be "Substantially Equivalent"

No

Could the New Characteristics Affect Safety or Effectiveness?

Yes

Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?

Yes

No

Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?

Yes

Are Performance Data Available to Assess Effects of New Characteristics?

Yes

No

Performance Data Required

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes

No

Are Performance Data Available to Assess Equivalence?

Yes

No

Performance Data Required

New Device Has New Intended Use

"Substantially Equivalent" Determination

510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Am) Devices Is Unclear.

This Decision Is Normally Based on Descriptive Information Alone, But Certain Information Is Sometimes Required.

*Date 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.
I. **Purpose**

The sponsor intends to market a laryngo-tracheal topical anesthesia applicator.

II. **Intended Use/Indications for Use**

From the Indications for Use form (see page 1):

[The device is intended] for the application of topical anesthetics to the oropharynx and upper airway region.

III. **Predicate devices**

The sponsor has claimed the following predicate device:

K894755: Astra Disposable Spray Cannula.

IV. **Device Description**

A. **Summary**

<table>
<thead>
<tr>
<th>Life-supporting or life-sustaining?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterile?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
### B. Design/Specifications

The subject device is a laryngo-tracheal topical anesthesia applicator. The device includes a tube with a female Luer connector at one end and an atomizer tip at the other end. A stainless steel wire enclosed in the wall of the tube allows a physician to bend the tube to a desired angle before use. A previously cleared syringe (K980987) is used to administer anesthesia through the device.

The atomizer tip in the device was not adequately described. The amendment of September 7 included detailed drawings of the atomizer tip. The device is now adequately described.

### C. Labeling

The original labeling was not acceptable because it did not include a statement of the indications for use of the device or the caution statement required for prescription devices. The amendment of September 7 included revised labeling with a statement of the indications for use of the device and the required caution statement. The revised labeling is adequate.

### D. Biocompatibility

No biocompatibility information was originally provided in the file. The sponsor indicated that all of the materials used were USP Class VI plastics. We requested additional biocompatibility information for the PVC and the polycarbonate used in the device. The amendment of September 7 included biocompatibility data for the polycarbonate used in the device, and on September 14, a biocompatibility certification was provided for the PVC used. The biocompatibility information is adequate.

### G. Certifications/Statements

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Truthful and accurate statement?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>510(k) summary or statement?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Indications for use form?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
V. **Substantial Equivalence**

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is Product A Device</td>
<td>YES</td>
<td>If NO = Stop</td>
</tr>
<tr>
<td>2. Is Device Subject To 510(k)?</td>
<td>YES</td>
<td>If NO = Stop</td>
</tr>
<tr>
<td>3. Same Indication Statement?</td>
<td>YES</td>
<td>If YES = Go To 5</td>
</tr>
<tr>
<td>4. Do Differences Alter The Effect Or Raise New Issues Of Safety Or Effectiveness?</td>
<td></td>
<td>If YES = Stop NE</td>
</tr>
<tr>
<td>5. Same Technological Characteristics?</td>
<td>YES</td>
<td>If YES = Go To 7</td>
</tr>
<tr>
<td>6. Could The New Characteristics Affect Safety Or Effectiveness?</td>
<td></td>
<td>If YES = Go To 8</td>
</tr>
<tr>
<td>7. Descriptive Characteristics Precise Enough?</td>
<td>YES</td>
<td>If NO = Go To 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If YES = Stop SE</td>
</tr>
<tr>
<td>8. New Types Of Safety Or Effectiveness Questions?</td>
<td></td>
<td>If YES = Stop NE</td>
</tr>
<tr>
<td>9. Accepted Scientific Methods Exist?</td>
<td></td>
<td>If NO = Stop NE</td>
</tr>
<tr>
<td>10. Performance Data Available?</td>
<td></td>
<td>If NO = Request Data</td>
</tr>
</tbody>
</table>

**Explanations to "Yes" and "No" Answers to Questions as Needed**

"Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation:

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

VI. Recommendation

I believe that the subject device is substantially equivalent to 21 CFR 888.5170. Classification should be based on 73 CCT/II (two).

William A. Noe
9/14/00
William A. Noe
## Screening Checklist

For all Premarket Notification 510(k) Submissions

### Device Name:

<table>
<thead>
<tr>
<th>Submitter (Company):</th>
</tr>
</thead>
</table>

**Items which should be included**

*(circle missing & needed information)*

<table>
<thead>
<tr>
<th></th>
<th>SPECIAL</th>
<th>ABBREVIATED</th>
<th>TRADITIONAL</th>
<th>IF ITEM IS NEEDED AND IS MISSING</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>

#### 1. Cover Letter clearly identifies Submission as:

- a) **"Special 510(k): Device Modification"**
- b) **"Abbreviated 510(k)"**
- c) **Traditional 510(k)**

#### 2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS

<table>
<thead>
<tr>
<th>Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
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</table>

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

- a) trade name, classification name, establishment registration number, device class
- b) OR a statement that the device is not yet classified
- c) identification of legally marketed equivalent device
- d) compliance with Section 514 - performance standards
- e) address of manufacturer
- f) Truthful and Accurate Statement
- g) Indications for Use enclosure
- h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*
- i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*
- j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals
- k) Proposed Labeling:
  - i) package labeling (user info)
  - ii) statement of intended use
  - iii) advertisements or promotional materials
  - iv) MRI compatibility (if claimed)
  - v) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:
    - i) labeling
    - ii) intended use
    - iii) physical characteristics
    - iv) anatomical sites of use
    - v) performance (bench, animal, clinical) testing
    - vi) safety characteristics
- m) If kit, kit certification

#### 3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE

- a) Name & 510(k) number of legally marketed (unmodified) predicate device
- b) **STATEMENT - INTENDED USE AND INDICATIONS FOR**

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
### USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*

| If no - STOP not a special |

### Statement - Fundamental Scientific Technology of the Modified Device Has Not Changed*

### Design Control Activities Summary

#### i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis

#### ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

#### iii) A declaration of conformity with design controls. The declaration of conformity should include:

1. A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met

2. A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.

### Abbreviated 510(K): Special Controls/Conformance to Recognized Standards - Please Fill Out the Standards Abbreviated Form on the H Drive

<table>
<thead>
<tr>
<th>SPECIALS</th>
<th>ABBREVIATED</th>
<th>TRADITIONAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>YES</td>
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</table>

### a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type

### b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.

### c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:

#### i) An identification of the applicable recognized consensus standards that were met

#### ii) A specification, for each consensus standard, that all requirements were met, except for
### 5. Additional Considerations: (may be covered by Design Controls)

<table>
<thead>
<tr>
<th>a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) component &amp; material</td>
</tr>
<tr>
<td>ii) identify patient-contacting materials</td>
</tr>
<tr>
<td>iii) biocompatibility of final sterilized product</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>b) Sterilization and expiration dating information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) sterilization method</td>
</tr>
<tr>
<td>ii) SAL</td>
</tr>
<tr>
<td>iii) packaging</td>
</tr>
<tr>
<td>iv) specify pyrogen free</td>
</tr>
<tr>
<td>v) ETO residues</td>
</tr>
<tr>
<td>vi) radiation dose</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>c) Software validation &amp; verification:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) hazard analysis</td>
</tr>
<tr>
<td>ii) level of concern</td>
</tr>
<tr>
<td>iii) development documentation</td>
</tr>
<tr>
<td>iv) certification</td>
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</tbody>
</table>

*Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.*

Passed Screening: Yes ✔️ No ✗

Date: 11-21-16

Reviewer: [Signature]

Concurrence by Review Branch: [Signature]
THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Is Product A Device</td>
<td>If NO = Stop</td>
<td></td>
</tr>
<tr>
<td>2. Is Device Subject To 510(k)?</td>
<td>If NO = Stop</td>
<td></td>
</tr>
<tr>
<td>3. Same Indication Statement?</td>
<td>If YES = Go To 5</td>
<td></td>
</tr>
<tr>
<td>4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?</td>
<td>If YES = Stop NE</td>
<td></td>
</tr>
<tr>
<td>5. Same Technological Characteristics?</td>
<td>If YES = Go To 7</td>
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<tr>
<td>6. Could The New Characteristics Affect Safety Or Effectiveness?</td>
<td>If YES = Go To 8</td>
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</tr>
<tr>
<td>7. Descriptive Characteristics Precise Enough?</td>
<td>If NO = Go To 10</td>
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<td>8. New Types Of Safety Or Effectiveness Questions?</td>
<td>If YES = Stop NE</td>
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<tr>
<td>9. Accepted Scientific Methods Exist?</td>
<td>If NO = Stop NE</td>
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</tr>
<tr>
<td>10. Performance Data Available?</td>
<td>If NO = Request Data</td>
<td></td>
</tr>
<tr>
<td>11. Data Demonstrate Equivalence?</td>
<td>Final Decision:</td>
<td></td>
</tr>
</tbody>
</table>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.
1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION
# Internal Administrative Form

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
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<td>1. Did the firm request expedited review?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Did we grant expedited review?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you verified that the Document is labeled Class III for GMP purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. If, not, has POS been notified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Is the product a device?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Is the device exempt from 510(k) by regulation or policy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Is the device subject to review by CDRH?</td>
<td></td>
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</tr>
<tr>
<td>8. Are you aware that this device has been the subject of a previous NSE decision?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Are you aware of the submitter being the subject of an integrity investigation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. If, yes, consult the ODE Integrity Officer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #l91-2 and Federal Register 90N0332, September 10, 1991.)</td>
<td></td>
<td></td>
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</tbody>
</table>
TO:  Mr. William Noe  
FROM: Marshall Denton  
COMPANY: Food and Drug Administration  
DATE: 09-14-00  
FAX NUMBER: 301-480-4204  
PHONE NUMBER:  
TOTAL NO. OF PAGES INCLUDING COVER: 2  
RE: 510(k) K002255  
URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE  
NOTES/COMMENTS:  
Dear Mr. Noe,  
Attached is the information you requested for our file.  
Regards,  
Marshall Denton  

Sponsor,  
I will mail a copy today.  
Wa— 9/14/00
September 14, 2000

Mr. William Noe
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Dear Mr. Noe,

I have provided below the additional information that you requested for our 510 (k) submission number K002255:

(b) (4)

Please let me know if there is any additional information that you may require.

Sincerely,

[Signature]

Marshall T. Denton
VP and General Manager
September 5, 2000

Mr. William Noe
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Dear Mr. Noe,

I have provided below the additional information that you requested for our 510 (k) submission number K002255:

(b)(4)
Please let me know if there is any additional information that you may require.

Sincerely,

[Signature]

[Name]
VP and General Manager
APPENDIX I

LARYNGO-TRACHEAL MUCOSAL ATOMIZATION DEVICE DRAWINGS

TOTAL PAGES: 6
APPENDIX II

Revised Labeling:

MADgic™
Laryngo-Tracheal Mucosal Atomization Device

Catalog Numbers:
MAD600, MAD700

Made in the U.S.A.

INDICATIONS FOR USE:
Intended for the application of topical anesthetics to the oropharynx and upper airway region.

Single patient use only.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

INSTRUCTIONS FOR USE:
1. Disconnect MADgic™ from included syringe (MAD600 only).
2. Fill syringe with desired volume of solution and eliminate remaining air.
3. Connect the MADgic™ to the syringe. Eliminate air from tubing and bend tubing extension into desired position. Tubing will remain in fixed position.
4. Place the MADgic™ tip in the oropharyngeal cavity.
5. Compress the syringe plunger to spray atomized solution into the oropharyngeal cavity.
6. Re-use the MADgic™ on the same patient as needed, then discard.

MADgic™
Wolfe Tory Medical, Inc.
www.wolfe-tory.com

Wolfe Tory Medical, Inc.
Salt Lake City, UT 888-380-9808
www.wolfe-tory.com

P/N 70-xxxx Rev 04/00
APPENDIX III

BIOCOMPATABILITY TEST RESULTS

(b) (4)
July 25, 2000

WOLFE TORY MEDICAL, INC.
79 WEST 4500 SOUTH, SUITE 21
SALT LAKE CITY, UT 84107
ATTN: TIM WOLFE

510(k) Number: K002255
Received: 25-JUL-2000
Product: LARYNGO-TRACHEAL MUCOSAL ATOMIZATION DEVICE (MADGIC)

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/main.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

[Signature]
510(K) NOTIFICATION

Applicant: Tim Wolfe, MD - President
Wolfe Tory Medical, Inc.
79 West 4500 South, Suite 21
Salt Lake City, UT 84107
Phone: (801) 281-3000 Fax: (801) 281-0708

Contact Person: Tim Wolfe, MD
Application Date: 7/21/00

Truthful and Accurate Statement
[As required by 21 CFR 807.870(j)]

I certify that, in my capacity as President of Wolfe Tory Medical, Inc., I believe to the best of my knowledge, that all data and information as submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

Tim Wolfe M.D.
Typed

July 21, 2000
Date

510(k) Number
# Table of Contents

Company and Submission Information .............................................................. 3  
Statement of Indications for Use................................................................. 4  
Substantial Equivalence Comparison ......................................................... 5  
  Comparison to Predicate Device ............................................................... 6  
Labeling ........................................................................................................ 8  
References ................................................................................................... 9  

APPENDIX I  
Summary of Safety and Effectiveness
## Company and Submission Information

| Applicant                          | Tim Wolfe, MD - President  
<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>Wolfe Tory Medical, Inc.</td>
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<td></td>
<td>79 West 4500 South, Suite 21</td>
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<tr>
<td></td>
<td>Salt Lake City, UT 84107</td>
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<td></td>
<td>(801) 281-3000</td>
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<tr>
<td>Contact</td>
<td>Tim Wolfe, MD</td>
</tr>
<tr>
<td>Date Prepared</td>
<td>7/21/00</td>
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<td>Establishment Registration Number</td>
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<td>Type</td>
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<td>Trade Name</td>
<td>Laryngo-tracheal Mucosal Atomization Device (MADgic™)</td>
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<td>Predicate Devices</td>
<td>Astra Disposable Spray Cannula</td>
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<td>K894755</td>
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<td>Performance Standards</td>
<td>None established</td>
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510(k) Notification: MADgic™
July 2000

Statement of Indications for Use

Ver/3 - 4/24/96

Applicant: Wolfe Tory Medical, Inc.

510(k) Number (if known): 502255

Device Name: Laryngo-tracheal Mucosal Atomization Device (MADgic™)

Indications For Use:

Intended for the application of topical anesthetics to the oropharynx and upper airway region.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)
Substantial Equivalence Comparison

The process of intubation of the trachea leads to several physiologic and reflex responses by the human body[1]. These responses, consisting primarily of sympathetic stimulation and reflex gagging, coughing, and upper airway constriction or spasm, can lead to significant complications in selected patient populations[1-18]. Application of topical anesthetics to the oropharynx and upper airway prior to intubation results in substantial attenuation of all of the above adverse responses[2-18]. Devices required to effectively apply topical anesthetic to the upper airway are categorized by the FDA as “applicator (laryngo-tracheal), topical anesthesia” devices. Wolfe Tory Medical has developed such a device, called the Laryngo-Tracheal Mucosal Atomization Device (MADgic™) and is requesting premarket approval for sales and marketing of this device.

Background:

When a patient requires assisted ventilation for an elective operation or for respiratory failure, they are usually “intubated” with an endotracheal tube (ETT). During the process of endotracheal intubation, the distal end of a semirigid plastic tube (ETT) is inserted through the hypopharynx past the vocal cords and into the trachea. Once in the trachea the ETT has a balloon inflated at its distal tip, and air is insufflated into the trachea to ventilate the lungs. Endotracheal tube placement elicits numerous physiologic responses in the human organism. These include significant sympathoadrenal responses such as hypertension, tachycardia, elevation of intracranial pressure, increase in intraocular pressure and increase in circulating catecholamines (epinephrine and norepinephrine)[8, 10-18]. In non-pharmacologically paralyzed patients multiple reflex responses also occur including the gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-9].

In most situations, these responses do not lead to serious adverse patient outcomes. However, in a substantial number of cases these responses would be best avoided. For example, in a patient who requires an operation on their brain for a mass that is causing too much intracranial pressure, or on their eye for a ruptured globe, any increased intracranial or intraocular pressure could be devastating. Another situation that is frequently encountered is the patient who will clearly be a difficult intubation. In these patients pharmacologic paralysis could lead to failure to intubate, failure to ventilate and death or permanent brain damage. These patients must be intubated in a semi awake state, but often suffer from many of the reflex reactions described above, which lead to significantly more difficult intubation conditions.

The solution to these problems is the application of topical anesthetics to the oropharynx and upper airway. An extensive body of literature exists that demonstrates topical anesthetics attenuate the sympathetic response to intubation while simultaneously reducing or eliminating problems with gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-18]. These topical anesthetics are typically applied with laryngo-tracheal applicator type devices. Wolfe Tory Medical wishes to introduce a new laryngo-tracheal applicator called the Laryngo-Tracheal Mucosal Atomization Device MADgic™.
Laryngo-Tracheal Mucosal Atomization Device MADgic™

Description:
The Laryngo-Tracheal Mucosal Atomization Device is a disposable non-sterile device that converts a solution of topical anesthetic into a fine particle spray for application to mucosal surfaces. The device consists of an “atomizer” tip, a semirigid tubular extension, a standard luer lock adapter and a syringe. The clinician draws up the desired volume of topical anesthetic into the syringe, attaches it to the luer lock fitting of the atomizer, and manipulates the tubing extension into the desired position. As the syringe plunger is compressed, the anesthetic is forced into the tubular extension and out the atomizer tip. The tip takes the pressurized fluid column and begins spinning it, allowing the fluid to exit the small hole at the end in a cone shaped spray. The anesthetic mist is gently distributed onto the mucosal surface in front of this tip. Topical anesthesia application can begin in the mouth and pharynx, then proceed to the hypopharynx, epiglottis and vocal cords, larynx and trachea via direct visualization using a laryngoscope.

Component Parts:
The Laryngo-Tracheal Mucosal Atomization Device will be offered with or without a 5cc syringe.

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<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>Material Grade</th>
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<tr>
<td>5cc Syringe</td>
<td>Polypropylene</td>
<td>USP Class VI</td>
</tr>
<tr>
<td>Female Luer</td>
<td>Polycarbonate</td>
<td></td>
</tr>
<tr>
<td>Tubing</td>
<td>Polytetrafluoroethylene</td>
<td></td>
</tr>
<tr>
<td>Actuator adapter</td>
<td>Polycarbonate</td>
<td></td>
</tr>
<tr>
<td>Atomizer tip</td>
<td>Polycarbonate</td>
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</tr>
<tr>
<td>Wire</td>
<td>Stainless Steel</td>
<td>No patient, user, or fluid path contact.</td>
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<tr>
<td>Adhesive</td>
<td>Cyclohexanone</td>
<td>Medical – Reagent Grade</td>
</tr>
<tr>
<td>Adhesive</td>
<td>UV Cured</td>
<td>USP Class VI</td>
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Comparison to Predicate Device

<table>
<thead>
<tr>
<th>WT Laryngo-Tracheal Mucosal Atomization Device</th>
<th>Astra Disposable Spray Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage amount</strong></td>
<td>User controlled</td>
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<tr>
<td><strong>Delivery form</strong></td>
<td>Fine particle spray mist</td>
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<tr>
<td><strong>Cannula shape</strong></td>
<td>Semi-rigid</td>
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<tr>
<td><strong>Spray generated by</strong></td>
<td>Piston syringe</td>
</tr>
<tr>
<td><strong>Spray tip diameter</strong></td>
<td>0.157”</td>
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<tr>
<td><strong>Materials</strong></td>
<td>Polycarbonate and polyvinylchloride</td>
</tr>
<tr>
<td><strong>Disposable</strong></td>
<td>Yes</td>
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</table>
Conclusions:

The process of intubation of the trachea leads to several physiologic and reflex responses by the human body[1]. Application of topical anesthetics to the oropharynx and upper airway prior to intubation results in substantial attenuation of these adverse responses[2-18]. The Laryngo-Tracheal Mucosal Atomization Device safely, gently and effectively applies topical anesthetics to mucosal surfaces. Use of the Laryngo-Tracheal Mucosal Atomization Device MADgic™ to apply anesthetic to the upper airway will attenuate or eliminate these adverse physiologic and reflex responses leading to improved patient outcomes.
Sample Labeling:

**MADgic™**

Laryngo-Tracheal Mucosal Atomization Device

**Catalog Numbers:**
MAD600, MAD700

Made in the U.S.A.

**INSTRUCTIONS FOR USE:**

1. Disconnect MADgic™ from included syringe (MAD600 only).
2. Fill syringe with desired volume of solution and eliminate remaining air.
3. Connect the MADgic™ to the syringe. Eliminate air from tubing and bend tubing extension into desired position. Tubing will remain in fixed position.
4. Place the MADgic™ tip in the oropharyngeal cavity.
5. Compress the syringe plunger to spray atomized solution into the oropharyngeal cavity.
6. Re-use the MADgic™ on the same patient as needed, then discard.

MADgic™
Wolfe Tory Medical, Inc.
www.wolfe.tory.com
P/N 70-xxxx Rev 04/00

Single patient Use only
Rx Only

Wolfe Tory Medical, Inc.
Salt Lake City, UT 888-380-9808
www.wolfe.tory.com
References:

APPENDIX I

SUMMARY OF SAFETY AND EFFECTIVENESS

TOTAL PAGES: 3
510(K) Summary
Summary of Safety and Effectiveness

Company and Submission Information

| Applicant              | Wolfe Tory Medical, Inc.  
|                       | 79 West 4500 South, Suite 21  
|                       | Salt Lake City, UT 84107  
|                       | (801) 281-3000  
| Contact               | Tim Wolfe, MD  
| Date Prepared         | 7/21/00  
| Classification Name   | Applicator, laryngo-tracheal, topical anesthesia  
|                       | 73 CCT  
| Common/Usual Name     | Atomizer  
| Proprietary Name and  | Laryngo-Tracheal Mucosal Atomization Device (MADgic™)  
| Legally Marketed Device |  
| Device Description    | Disposable non-sterile device designed for atomizing topical solutions across the nasal and oropharyngeal mucous membranes.  
| Substantial Equivalence Device | Astra Disposable Spray Cannula  
|                       | K894755  

Comparison to Predicate Device

| WT Laryngo-Tracheal  
| Mucosal Atomization Device | Astra Disposable Spray Cannula  
| Dosage amount            | User controlled  
|                          | Dependent on pump, metered dosage.  
| Delivery form            | Fine particle spray mist  
| Cannula shape            | Semi-rigid  
| Spray generated by       | Piston syringe  
| Spray tip diameter       | 0.157"  
| Materials                | Polycarbonate and polyvinylchloride  
| Disposable               | Yes  
|                          | Polypropylene  

Summary of Research Findings

Endotracheal tube placement elicits numerous physiologic responses in the human organism. These include significant sympathoadrenal responses such as hypertension, tachycardia, elevation of intracranial pressure, increase in intraocular pressure and increase in circulating catecholamines (epinephrine and norepinephrine)[8, 10-18]. In non-pharmacologically paralyzed patients multiple reflex responses also occur including the gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-9]. In most situations, these responses do not lead to serious adverse patient outcomes. However, in a substantial number of cases these responses would be best avoided. The solution to these problems is the application of topical anesthetics to the oropharynx and upper airway. An extensive body of literature exists.
that demonstrates topical anesthetics attenuate the sympathetic response to intubation while simultaneously reducing or eliminating problems with gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-18]. These topical anesthetics are typically applied with laryngotracheal applicator type devices. Wolfe Tory Medical wishes to introduce a new laryngo-racheal applicator called the Laryngo-Tracheal Mucosal Atomization Device.

Conclusions

The process of intubation of the trachea leads to several physiologic and reflex responses by the human body[1]. Application of topical anesthetics to the oropharynx and upper airway prior to intubation results in substantial attenuation of these adverse responses[2-18]. The Laryngo-Tracheal Mucosal Atomization Device safely, gently and effectively applies topical anesthetics to mucosal surfaces. Use of the Laryngo-Tracheal Mucosal Atomization Device to apply anesthetic to the upper airway will attenuate or eliminate these adverse physiologic and reflex responses leading to improved patient outcomes.

References:


