

SEP 18 2000

510(k) Notification: MADgic™  
July 2000

## 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 Legally Marketed Device	Laryngo-Tracheal Mucosal Atomization Device (MADgic™)
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	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:

1. Kaplan, J.D. and D.P. Schuster, *Physiologic consequences of tracheal intubation*. Clin Chest Med, 1991. 12(3): p. 425-32.
2. Bulow, K., T.G. Nielsen, and J. Lund, *The effect of topical lignocaine on intubating conditions after propofol-alfentanil induction*. Acta Anaesthesiol Scand, 1996. 40(6): p. 752-6.
3. Dyson, D.H., *Efficacy of lidocaine hydrochloride for laryngeal desensitization: a clinical comparison of techniques in the cat*. J Am Vet Med Assoc, 1988. 192(9): p. 1286-8.
4. Mallick, A., S.N. Smith, and A.R. Bodenham, *Local anaesthesia to the airway reduces sedation requirements in patients undergoing artificial ventilation [see comments]*. Br J Anaesth, 1996. 77(6): p. 731-4.
5. McCrirrick, A. and J.A. Pracilio, *Awake intubation: a new technique [see comments]*. Anaesthesia, 1991. 46(8): p. 661-3.
6. Mongan, P.D. and R.D. Culling, *Rapid oral anesthesia for awake intubation*. J Clin Anesth, 1992. 4(2): p. 101-5.
7. Sidhu, V.S., et al., *A technique of awake fiberoptic intubation. Experience in patients with cervical spine disease [see comments]*. Anaesthesia, 1993. 48(10): p. 910-3.
8. Sutherland, A.D. and R.T. Williams, *Cardiovascular responses and lidocaine absorption in fiberoptic- assisted awake intubation*. Anesth Analg, 1986. 65(4): p. 389-91.
9. Viguera, M., et al., *[Efficacy of topical administration of lidocaine through a Malinckrodt Hi-Lo Jet tube in lessening cough during recovery from general anesthesia]*. Rev Esp Anesthesiol Reanim, 1992. 39(5): p. 316-8.
10. Gaumann, D.M., et al., *Effects of topical laryngeal lidocaine on sympathetic response to rigid panendoscopy under general anesthesia*. ORL J Otorhinolaryngol Relat Spec, 1992. 54(1): p. 49-53.

11. Giorgi, L., et al., [*Topical laryngo-tracheal anesthesia and intraocular pressure in anesthesia for ophthalmic surgery*]. *Minerva Anesthesiol*, 1994. 60(1-2): p. 43-7.
12. Konrad, C., et al., *Is an alkalized lignocaine solution a better topical anaesthetic for intratracheal application?* *Eur J Anaesthesiol*, 1997. 14(6): p. 616-22.
13. Latorre, F., et al., [*Fiberoptic intubation and stress*]. *Anaesthesist*, 1993. 42(7): p. 423-6.
14. Lehtinen, A.M., et al., *Effect of intratracheal lignocaine, halothane and thiopentone on changes in plasma beta-endorphin immunoreactivity in response to tracheal intubation*. *Br J Anaesth*, 1984. 56(3): p. 247-50.
15. Stevens, J.B., P.A. Vories, and S.C. Walker, *Nebulized tetracaine attenuates the hemodynamic response to tracheal intubation*. *Acta Anaesthesiol Scand*, 1996. 40(6): p. 757-9.
16. Stoelting, R.K., *Circulatory response to laryngoscopy and tracheal intubation with or without prior oropharyngeal viscous lidocaine*. *Anesth Analg*, 1977. 56(5): p. 618-21.
17. Venus, B., V. Polassani, and C.G. Pham, *Effects of aerosolized lidocaine on circulatory responses to laryngoscopy and tracheal intubation*. *Crit Care Med*, 1984. 12(4): p. 391-4.
18. Yusa, T., et al., [*Effects of intratracheal lidocaine spray on circulatory responses to endotracheal intubation*]. *Masui*, 1990. 39(10): p. 1325-32.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 18 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.

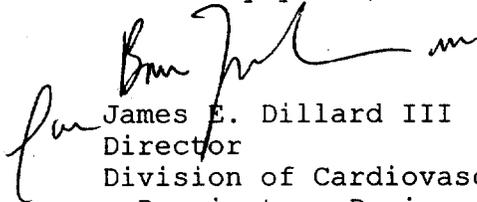
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Tim Wolfe

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,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name and title.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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): 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.

PRESCRIPTION USE    or     OVER-THE-COUNTER USE

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

*[Signature]*  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K002255

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): 1002055-A2

To: Division Director: AN/DCRD

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). Copy of faxed biocompatibility certification.

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 Noe  
Date: 9/25/00

Draft #2 : 9/8/99  
Draft #3: 1/3/00

SEP 25 2000

K002255-1A2



Records Processed under FOIA Request # 2015-8217; Released by CDRH on 11-9-2015  
**WOLFE TORY  
MEDICAL, INC.**

Salt Lake City, Utah 84107  
Phone: 801-281-3000  
Fax: 801-281-0708  
www.wolfetory.com

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:



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

Sincerely,

Marshall T. Denton  
VP and General Manager

REMOVED  
20 SEP 00 14 18  
FDA/CDRH/OCE/DID

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

8/20



SEP 18 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

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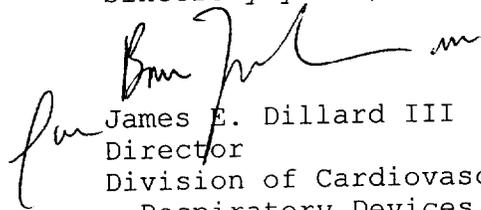
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Tim Wolfe

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

2

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): 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.

PRESCRIPTION USE      or       OVER-THE-COUNTER USE

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

*fu* *Frank Johnson*  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K002255

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) William A. NOE

Subject: 510(k) Number 1002255

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.

*Sargent 9/15*

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 Anesthesia Applicator (Larynx - Tracheal)  
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

73 CCT/II (Two)

Review: [Signature]  
(Branch Chief)

ADDB  
(Branch Code)

9/18/00  
(Date)

File: [Signature]  
(Division Director)

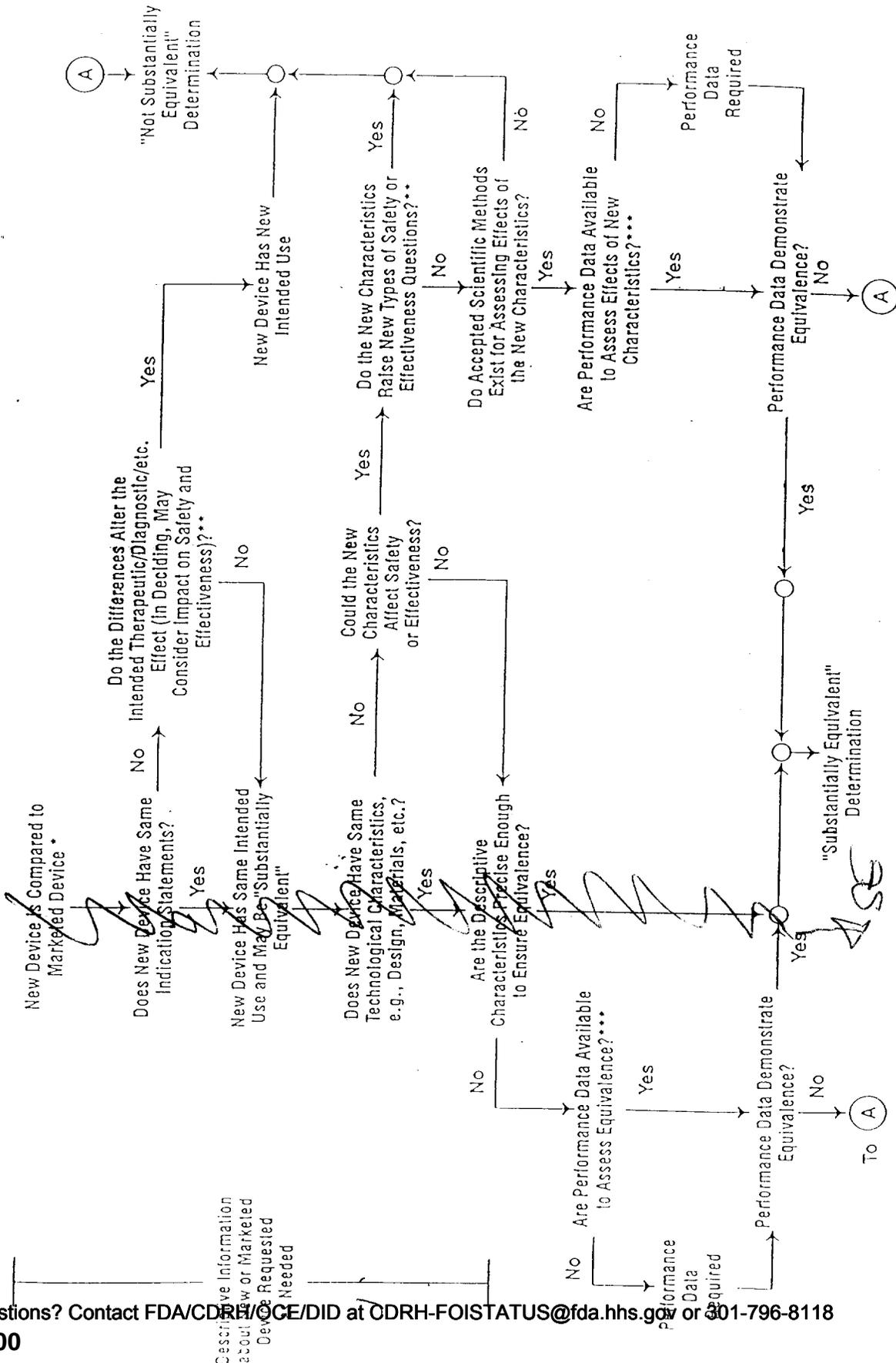
9/18/00  
(Date)

For questions, contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

4

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 801-796-8118



510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Am Reclassified Post-Amendments) Devices is Unclear.

\*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Technical Information is Sometimes Required.

\*\*\* Dat

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



**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification [510(k)] Review**

**K002255**

*Bozard 9/15.*

Date: September 14, 2000  
To: The Record  
From: William A. Noe, Electrical Engineer

Office: HFZ-450  
Division: DCRD/ADDG

Company Name: Wolfe Tory Medical, Inc.  
Device Name: Laryngo-tracheal Mucosal Atomization Device (MADgic™)  
Contact: Tim Wolfe, M.D.  
Phone: (801) 281-3000  
Fax: (801) 281-0708

**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**

Life-supporting or life-sustaining?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Implant?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Sterile?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

6

Single use?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Prescription use?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Home use or portable?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Drug or biological combination product?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Kit?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Software driven?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Electrically Operated?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

**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**

Truthful and accurate statement?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
510(k) summary or statement?	<input checked="" type="checkbox"/> Summary	<input type="checkbox"/> Statement
Indications for use form?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

**V. Substantial Equivalence**

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

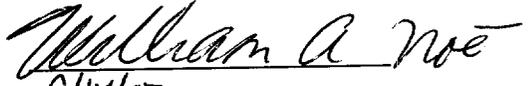
**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS AS NEEDED**  
**"yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation**

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 868.5170. Classification should be based on 73 CCT/II (two).

  
9/14/00  
William A. Noe

## Screening Checklist For all Premarket Notification 510(k) Submissions

<b>Device Name:</b>							<b>K</b>						
<b>Submitter (Company):</b>													
<b>Items which should be included (circle missing &amp; needed information)</b>						<b>S P E C I A L</b>	<b>A B B R E V I A T E D</b>	<b>T R A D I T I O N A L</b>	<b>✓ IF ITEM IS NEEDED AND IS MISSING</b>				
						YES	NO	YES		NO	YES	NO	
<b>1. Cover Letter clearly identifies Submission as:</b> a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5			GO TO # 4,5		<input checked="" type="checkbox"/>
<b>2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS</b>								<b>✓ IF ITEM IS NEEDED</b>					
<b>Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)</b>						NA		YES		NO		<b>AND IS MISSING</b>	
						SPECIALS		ABBREVIATED		TRADITIONAL			
						YES	NO	YES	NO	YES	NO		
a) trade name, classification name, establishment registration number, device class													
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator							
c) identification of legally marketed equivalent device						NA							
d) compliance with Section 514 - performance standards						NA							<input checked="" type="checkbox"/>
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													<input checked="" type="checkbox"/>
iii) advertisements or promotional materials													
i) MRI compatibility (if claimed)													
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:													
i) Labeling													<input checked="" type="checkbox"/>
ii) intended use													
iii) physical characteristics													<input checked="" type="checkbox"/>
iv) anatomical sites of use													<input checked="" type="checkbox"/>
v) performance (bench, animal, clinical) testing						NA							<input checked="" type="checkbox"/>
vi) safety characteristics						NA							<input checked="" type="checkbox"/>
m) If kit, kit certification													
<b>3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>													
a) Name & 510(k) number of legally marketed (unmodified) predicate device													0
b) STATEMENT - INTENDED USE AND INDICATIONS FOR													

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
c) <b>STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>				* If no - STOP not a special
d) 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.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE</b>							
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							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							✓
ii) identify patient-contacting materials							✓
iii) biocompatibility of final sterilized product							✓
b) Sterilization and expiration dating information:							
i) sterilization method							✓
ii) SAL							✓
iii) packaging							✓
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

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: 7-31-80

Reviewer: Kenneth R. Romo  
 Concurrence by Review Branch: \_\_\_\_\_

REVISED:3/14/95

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

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

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

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

14

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

15

# WOLFE TORY MEDICAL INC

79 WEST 4500 SOUTH, SUITE 21  
SALT LAKE CITY, UTAH 84107  
PHONE: 801-281-3000  
FAX: 801-281-0708  
TOLL FREE: 888-380-9808  
WEB SITE: WWW.WOLFETORY.COM

## FACSIMILE TRANSMITTAL SHEET

TO: Mr. William Noe	FROM: Marshall Denton
COMPANY: Food and Drug Administration	DATE: 09-14-00
FAX NUMBER: 301-480-4204	TOTAL NO. OF PAGES INCLUDING COVER: 2
PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
RE: 510(k) K002255	YOUR REFERENCE NUMBER:

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.  
will mail a copy  
today.*

*Wa  
9/14/00*

*16*



**WOLFE TORY  
MEDICAL, INC.**

79 West 4500 South, Suite 21  
Salt Lake City, Utah 84107  
Phone: 801-281-3000  
Fax: 801-281-0708  
www.wolfetory.com

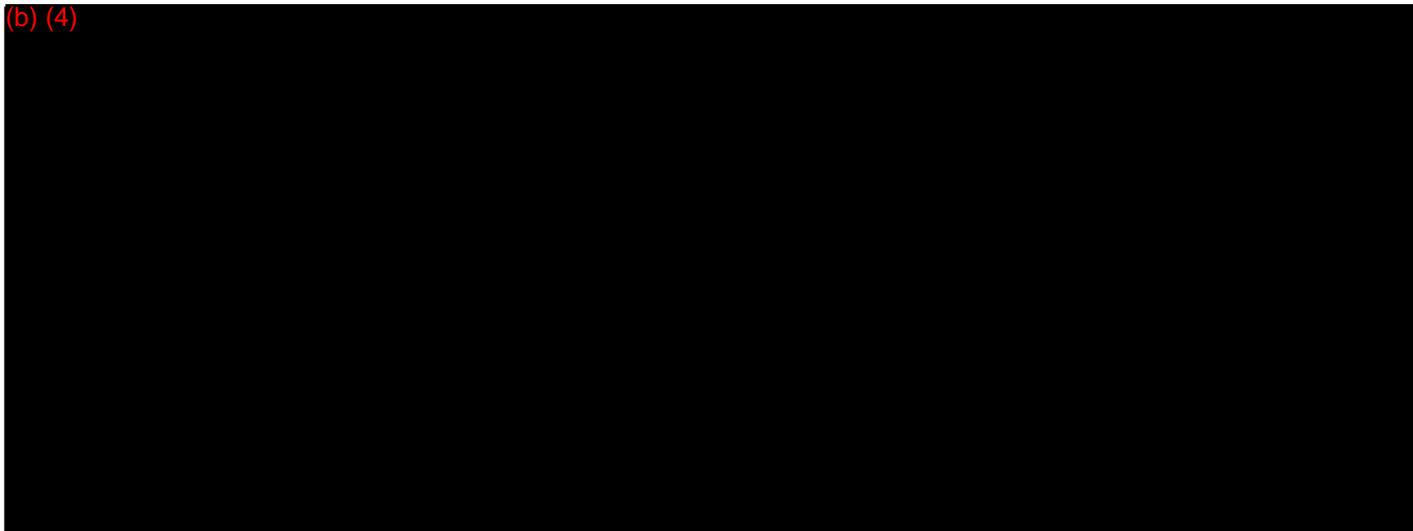
September 14, 2000

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,

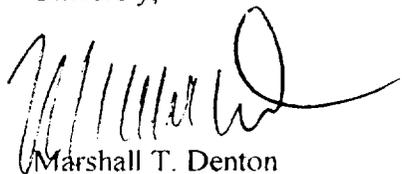
I have provided below the additional information that you requested for our 510 (k) submission number K002255:

(b) (4)



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

Sincerely,



Marshall T. Denton  
VP and General Manager

17

K002255/A1



**WOLFE TORY  
MEDICAL, INC.**

FDA/CDRH/OCE/DID

79 West 4500 South, Suite 21  
Salt Lake City, Utah 84107  
Phone: 801-281-3000  
Fax: 801-281-0708  
www.wolfeory.com

SEP 7 8 52 AM '00

RECEIVED

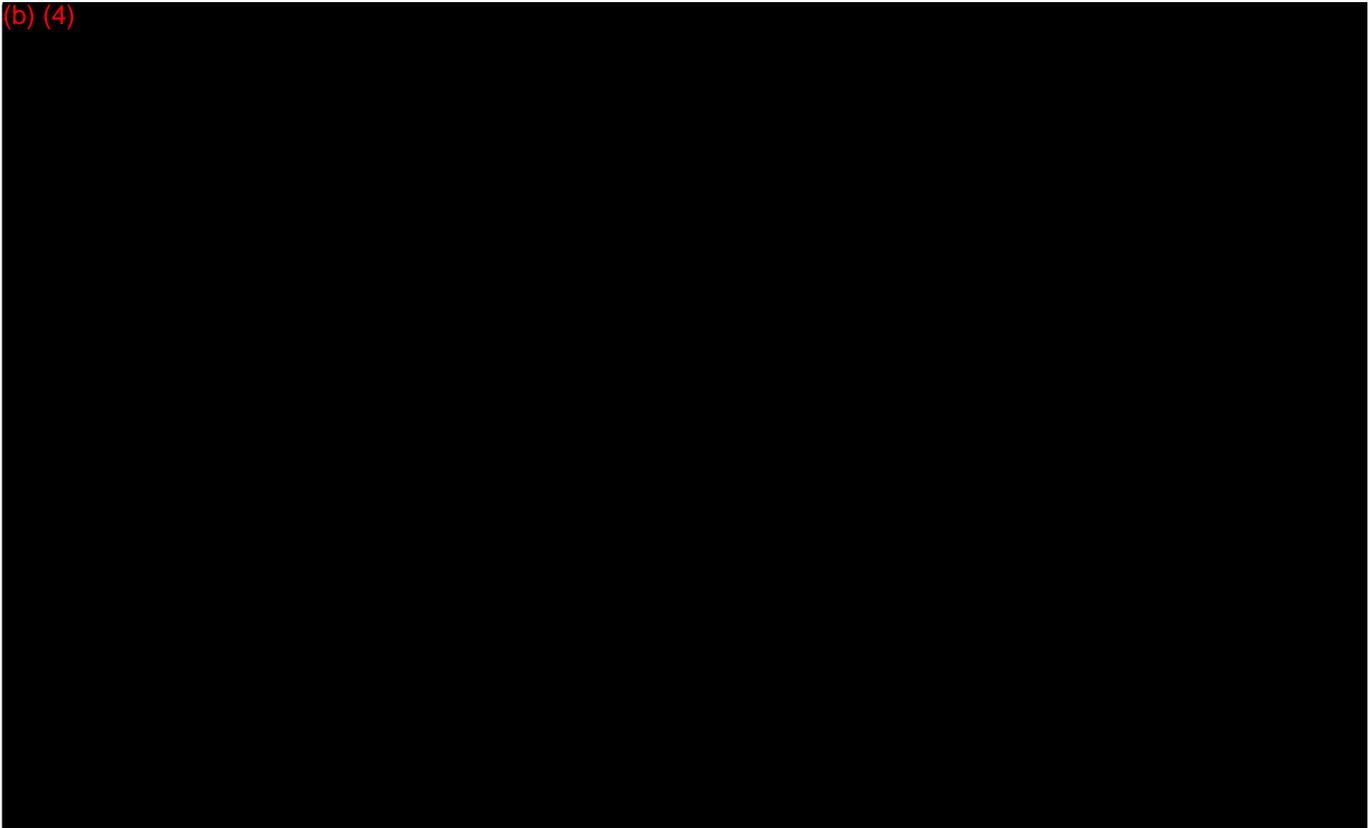
September 5, 2000

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,

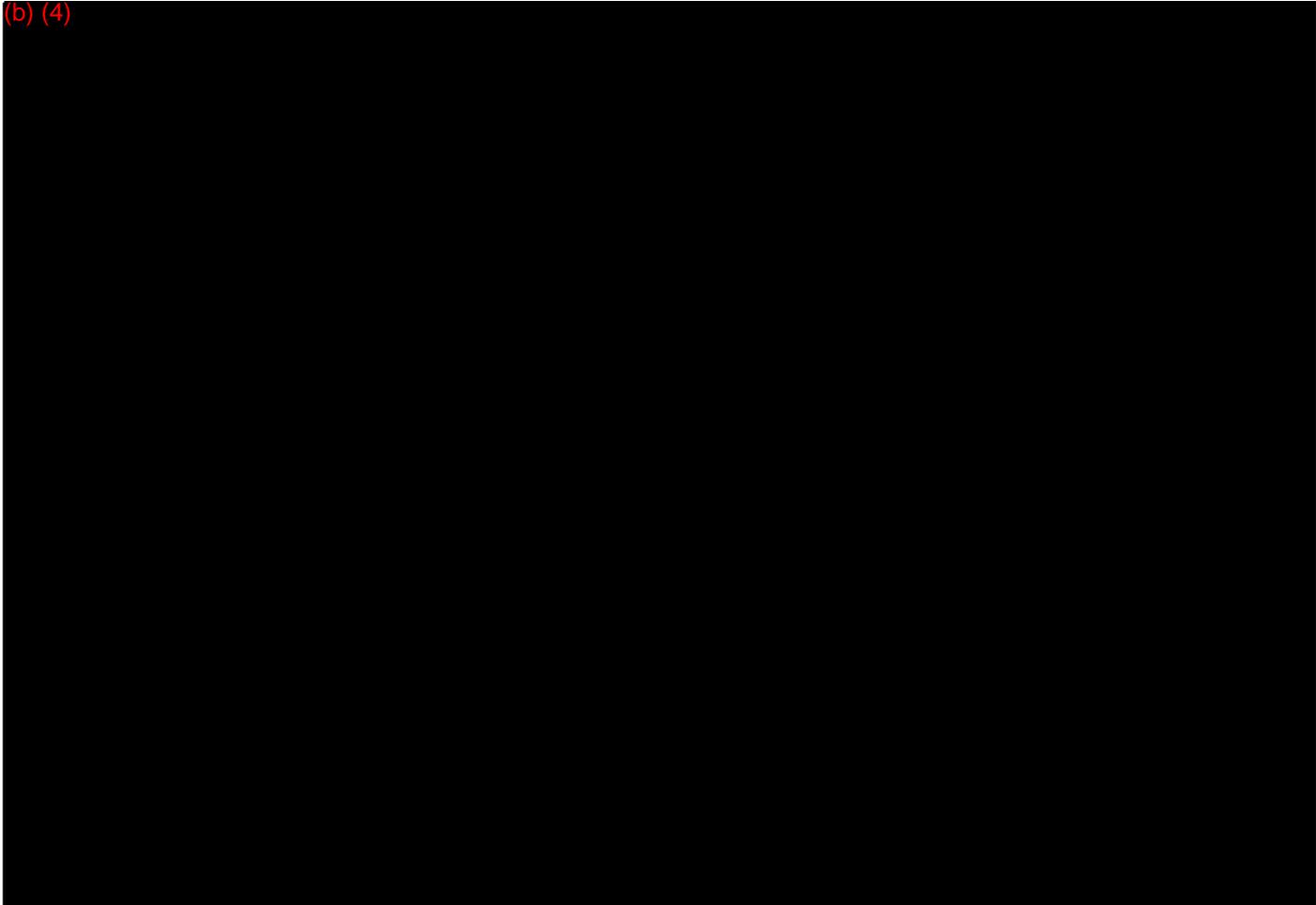
I have provided below the additional information that you requested for our 510 (k) submission number K002255:

(b) (4)



B

(b) (4)



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

Sincerely,

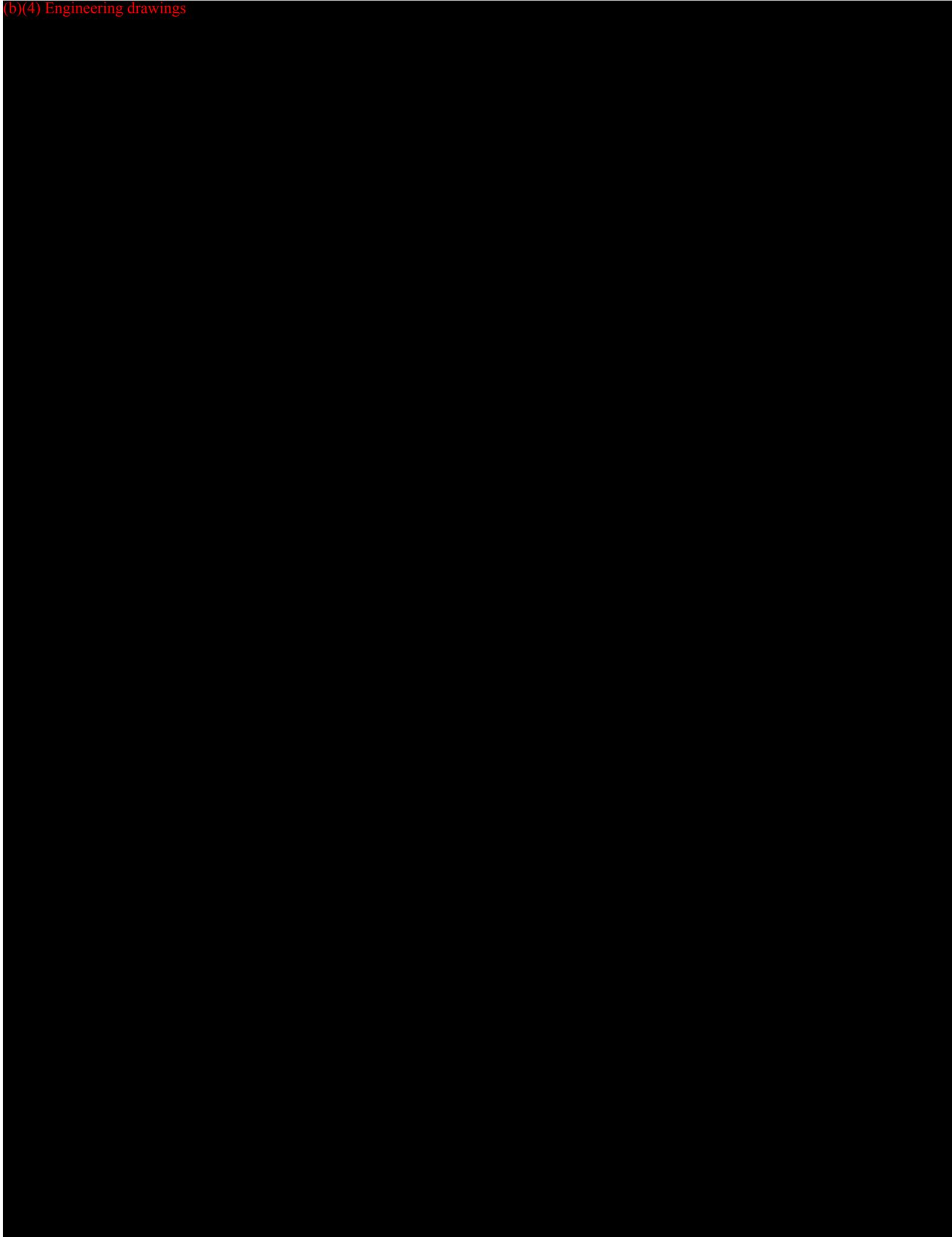


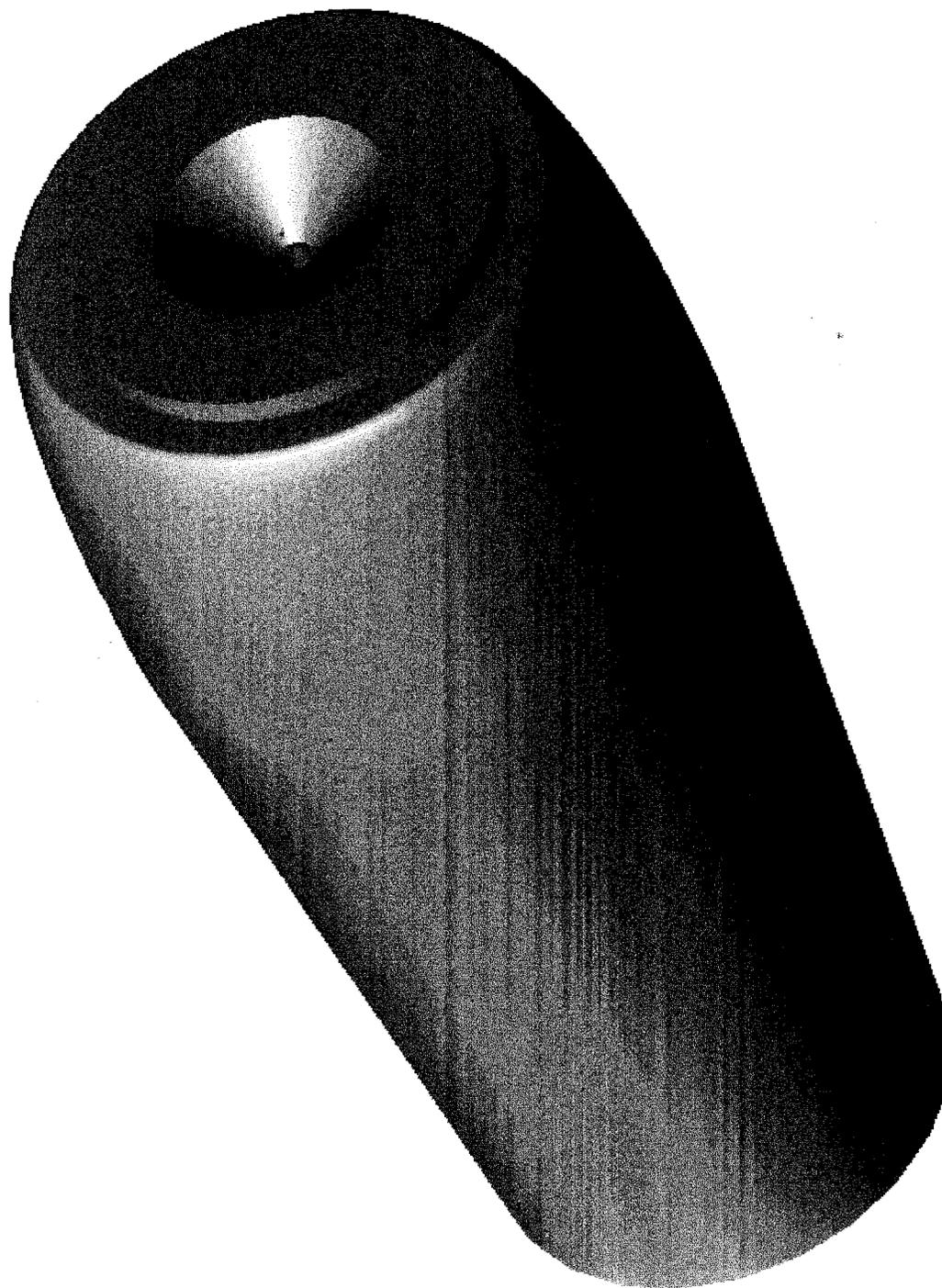
Marshall T. Denton  
VP and General Manager

# APPENDIX I

## LARYNGO-TRACHEAL MUCOSAL ATOMIZATION DEVICE DRAWINGS

TOTAL PAGES: 6





Laryngo-Tracheal Mucosal Atomization  
Device (Two Component Spray Head  
Assembly Only)  
3-D View

Figure 2.

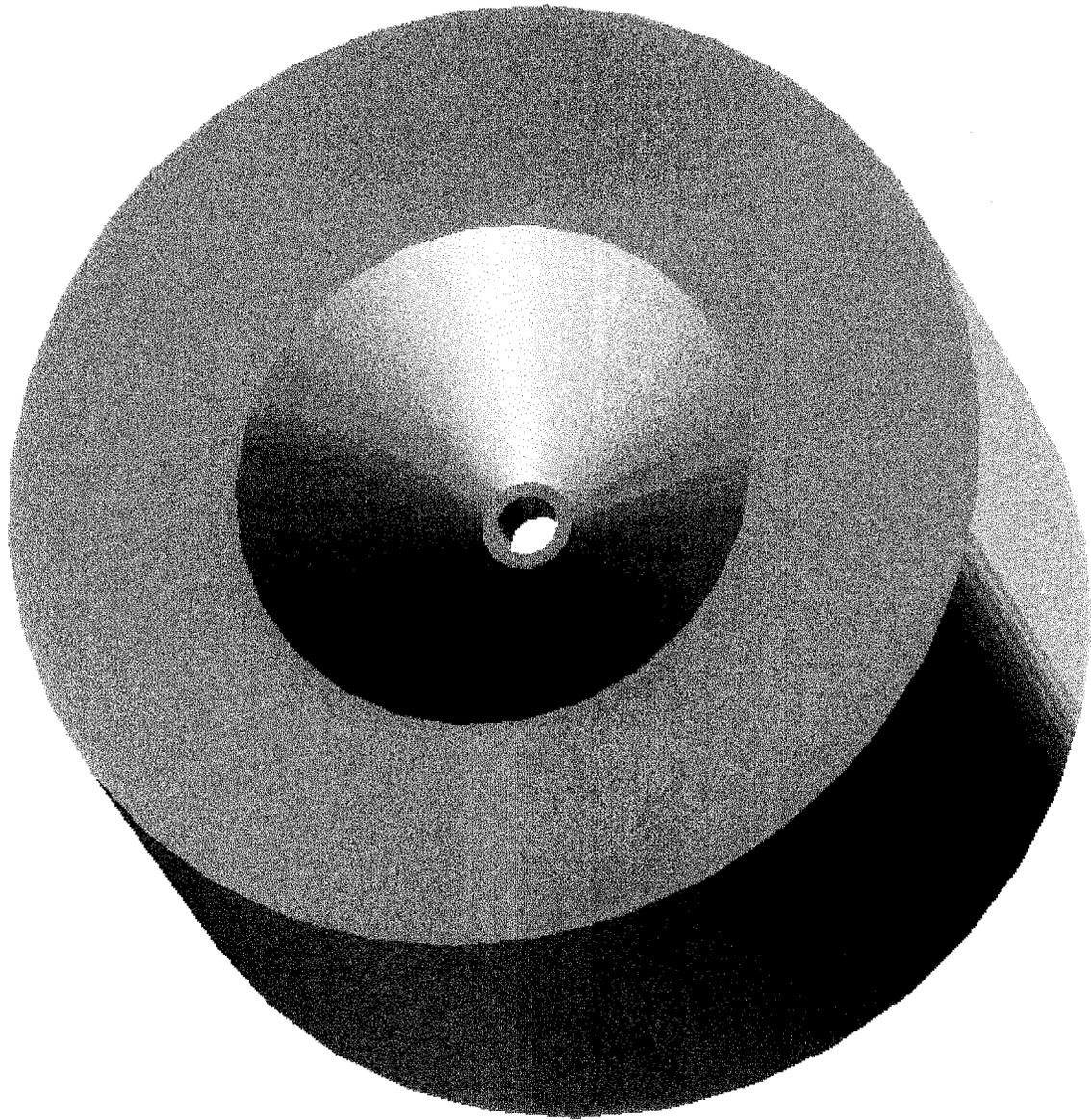
22



Laryngo-Tracheal Mucosal Atomization  
Device (Spray Head Tip Only)  
Bottom 3-D View of Spray Head Tip  
showing inside swirling chamber

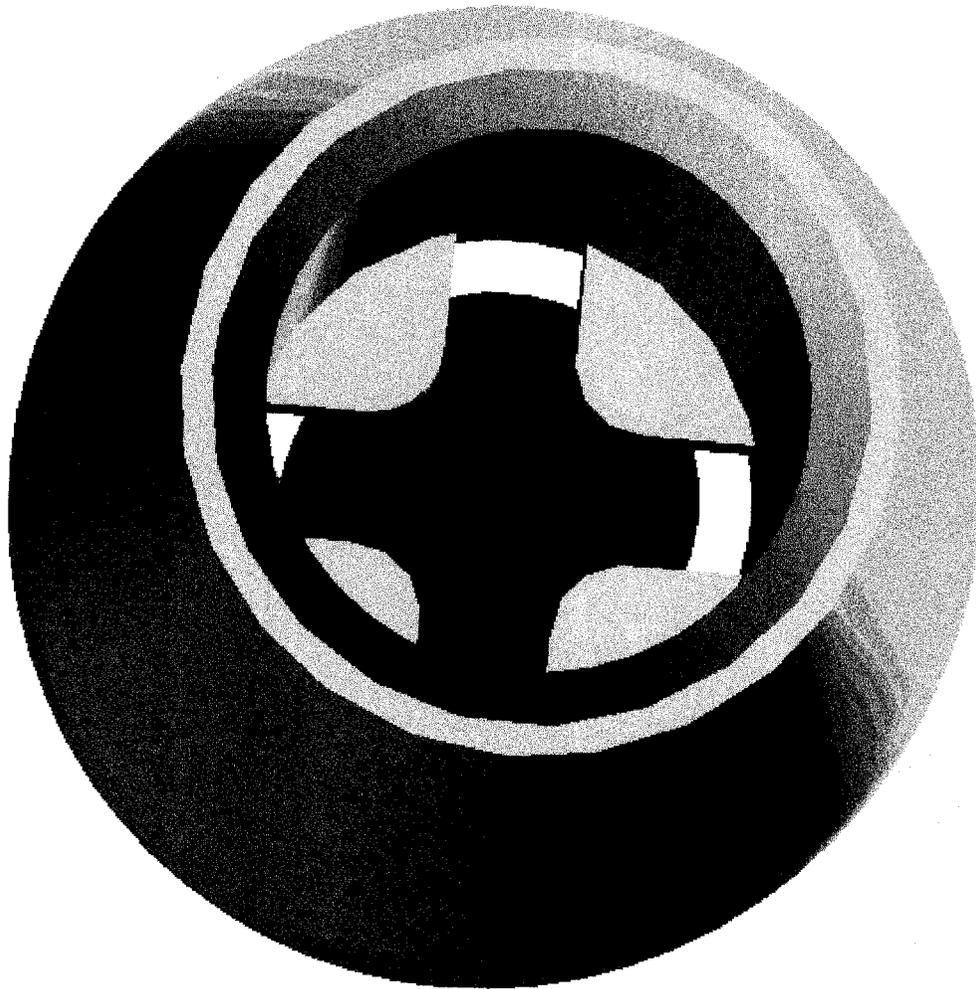
Figure 3.

23



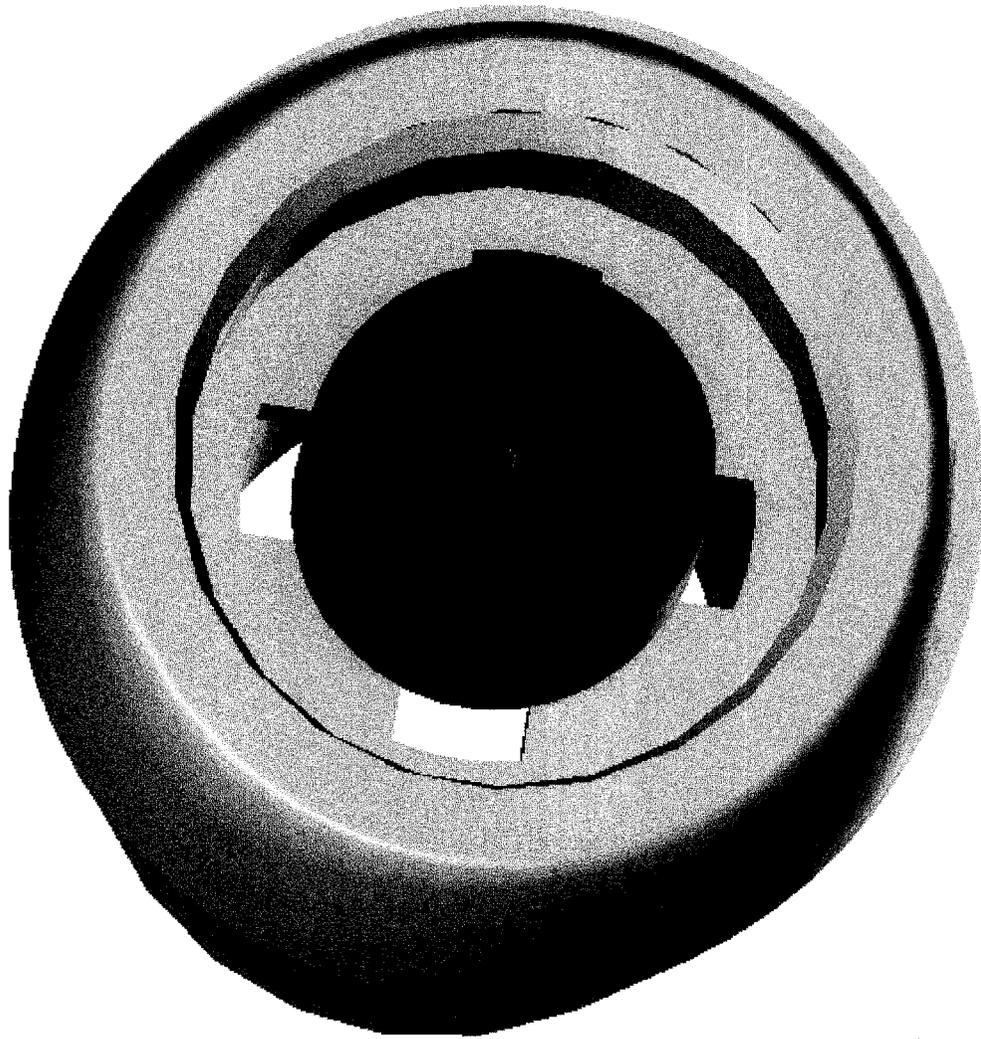
Laryngo-Tracheal Mucosal Atomization  
Device (Spray Head Tip Only)  
Top 3-D View of Spray Head Tip showing  
fluid exit port

Figure 4.



Laryngo-Tracheal Mucosal Atomization  
Device (Spray Head Body Only)  
Bottom 3-D view of Spray Head Body  
showing Tubing pocket.

Figure 5.



Laryngo-Tracheal Mucosal Atomization  
Device (Spray Head Body Only)  
Top 3-D view of Spray Head Body  
showing Spray Head Tip Cavity.

Figure 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.

Wolfe Tory Medical, Inc.  
Salt Lake City, UT 888-380-9808  
[www.wolfetory.com](http://www.wolfetory.com)

### 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.wolfetory.com](http://www.wolfetory.com)  
P/N 70-xxxx Rev 04/00

## APPENDIX III

### BIOCOMPATABILITY TEST RESULTS

(b) (4)



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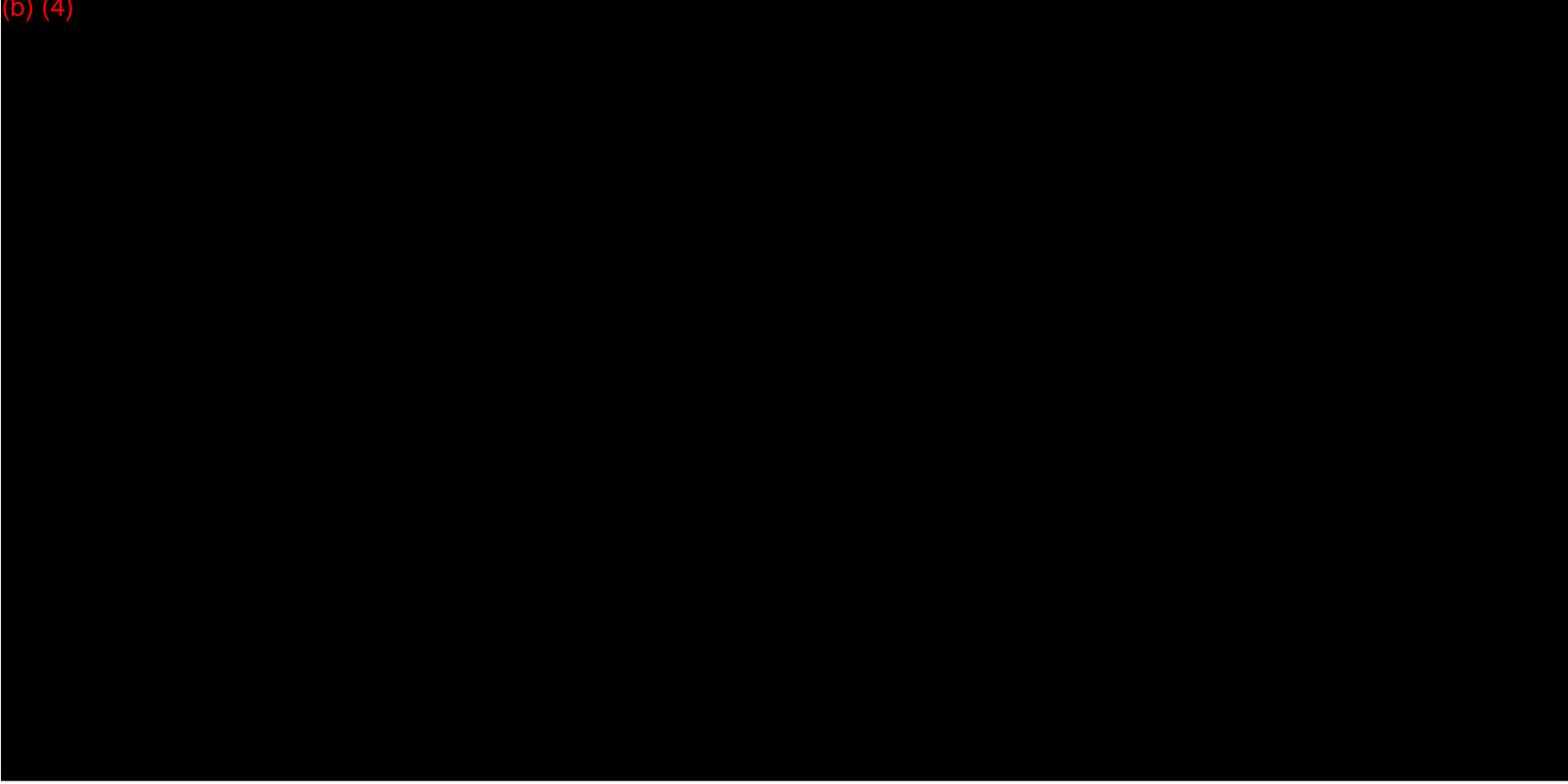










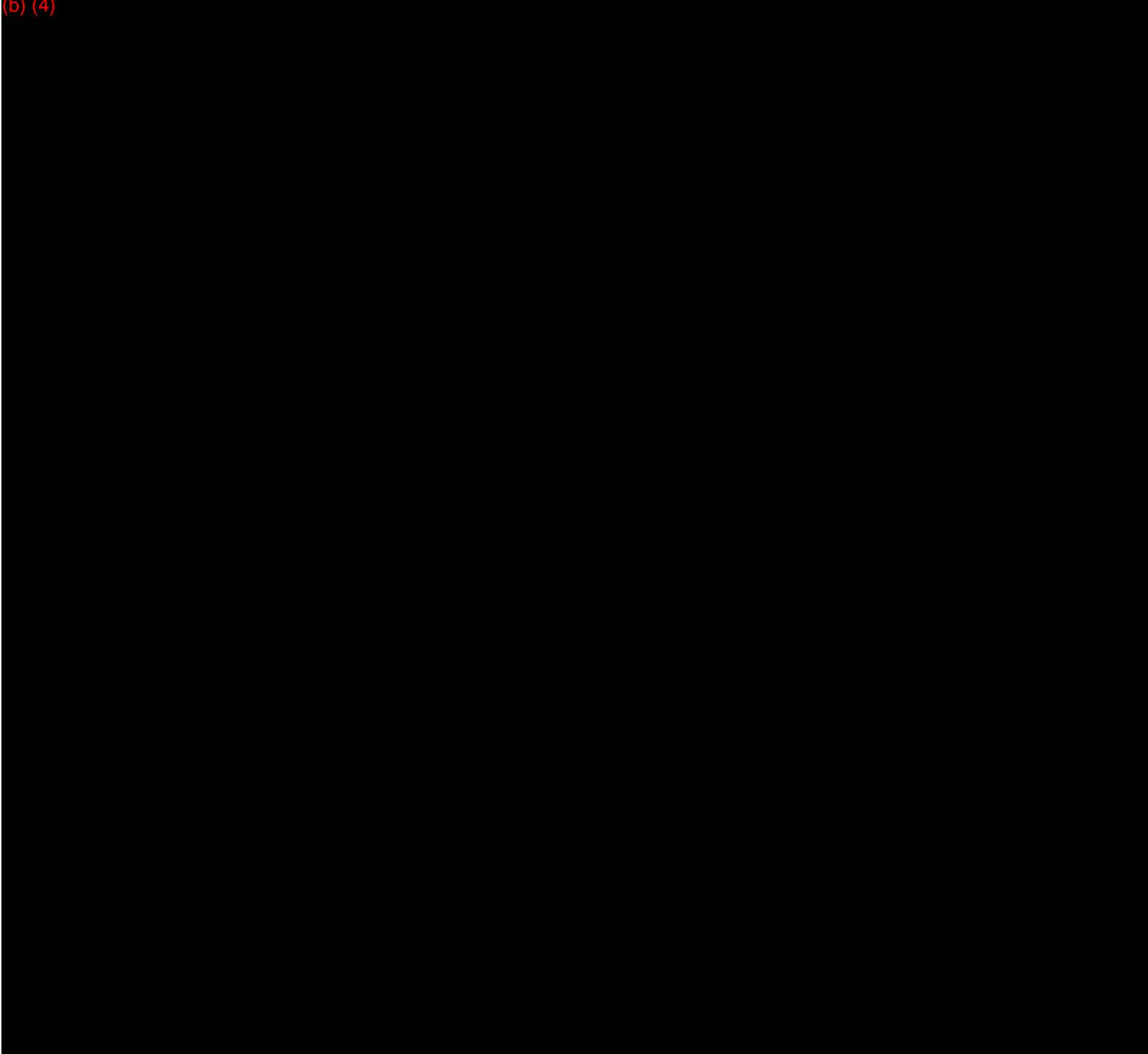


UN: 2721.00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

*Pg 6 of 47*

6 34



UN: 2721.00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

7 31







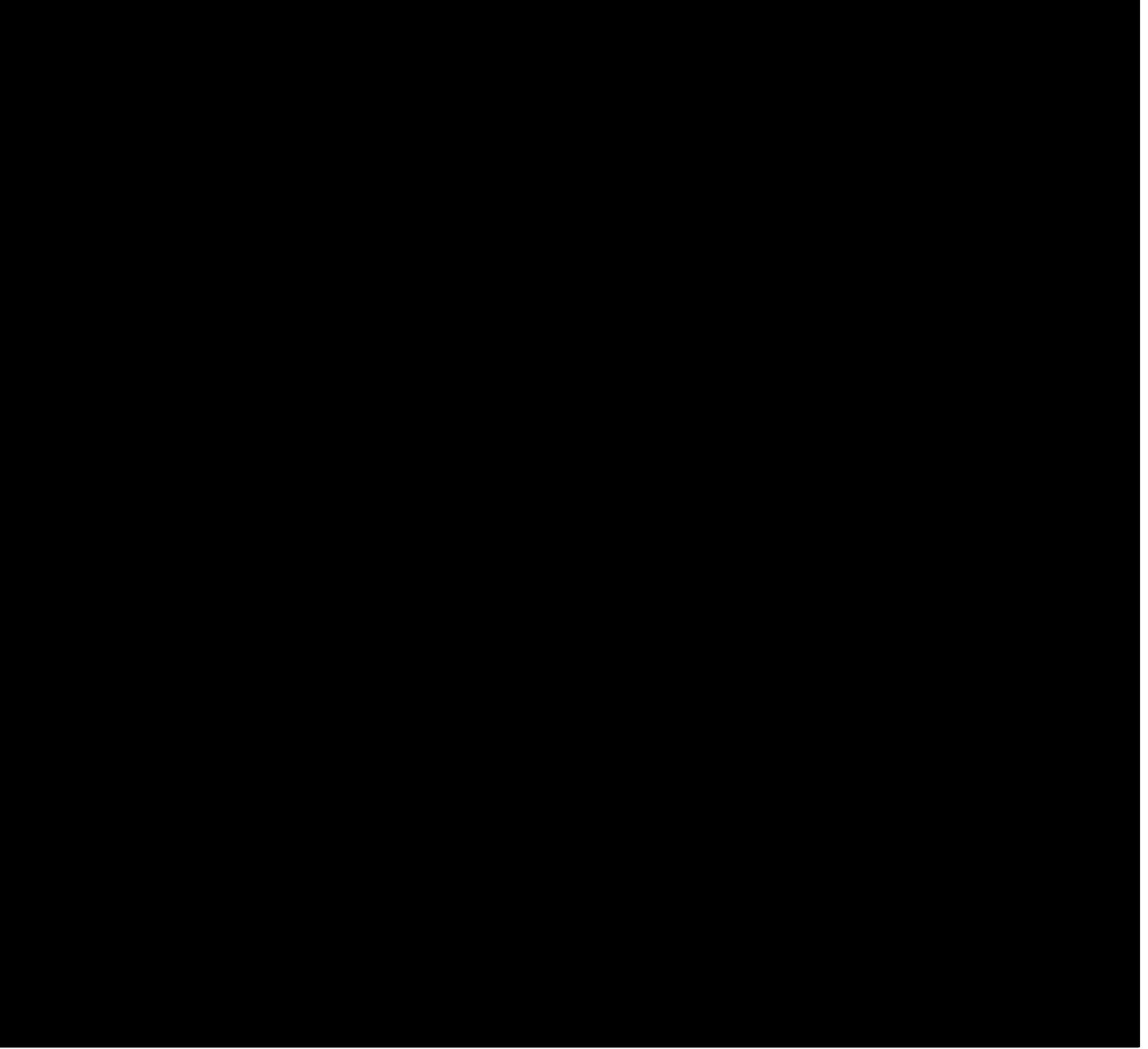






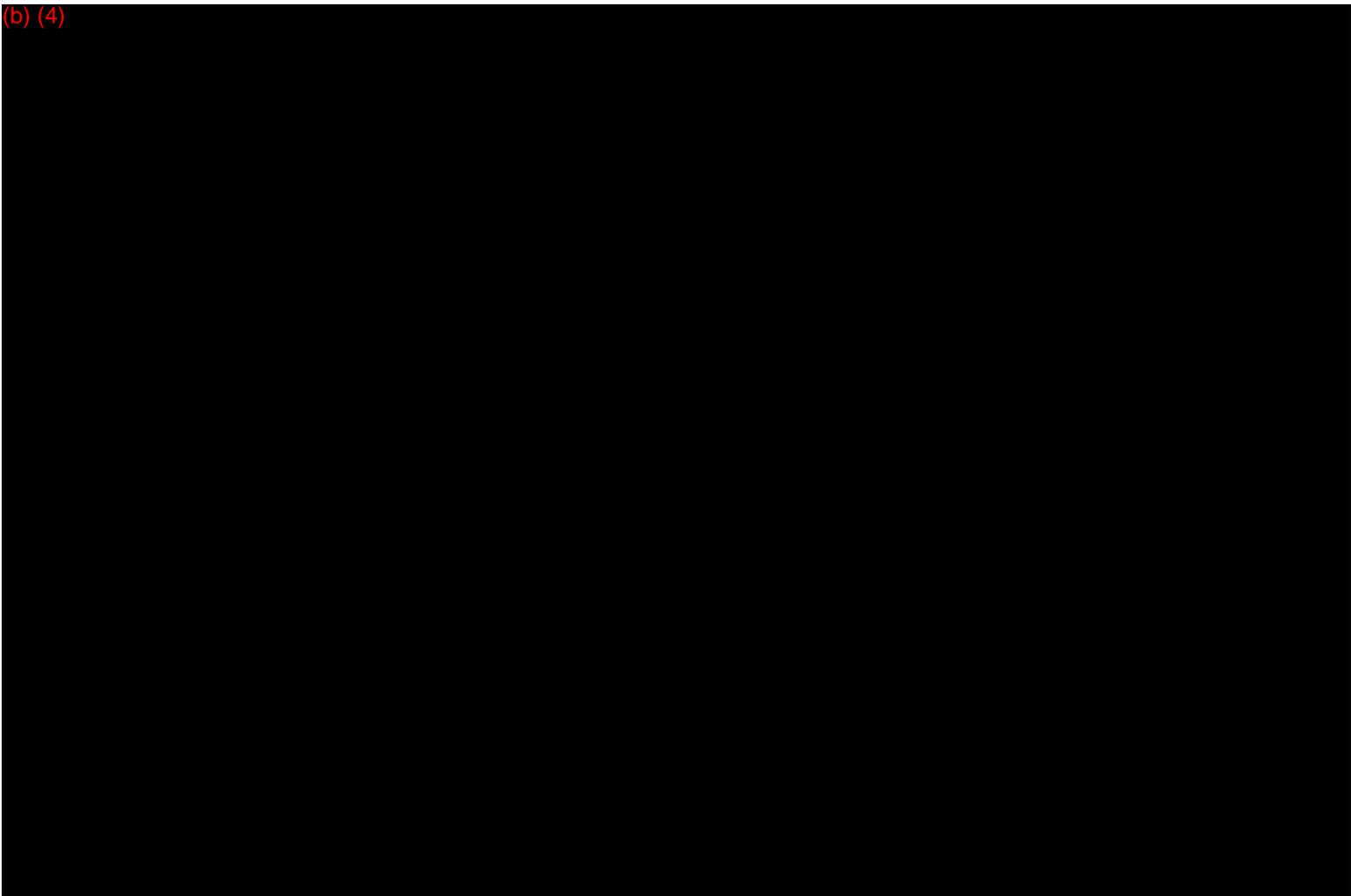






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*Pg 16 of 47*



LIN: 2727.00

10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

W





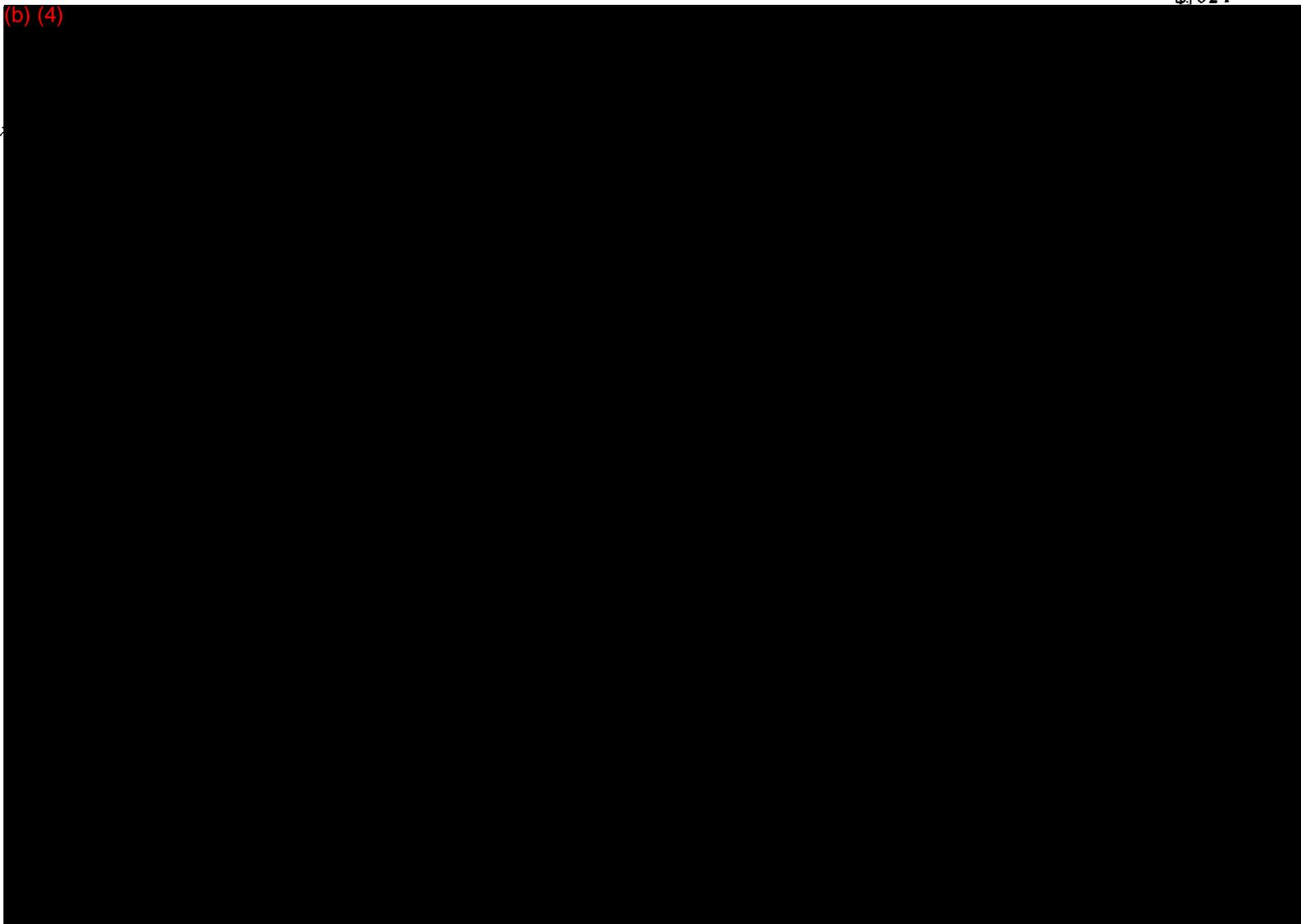






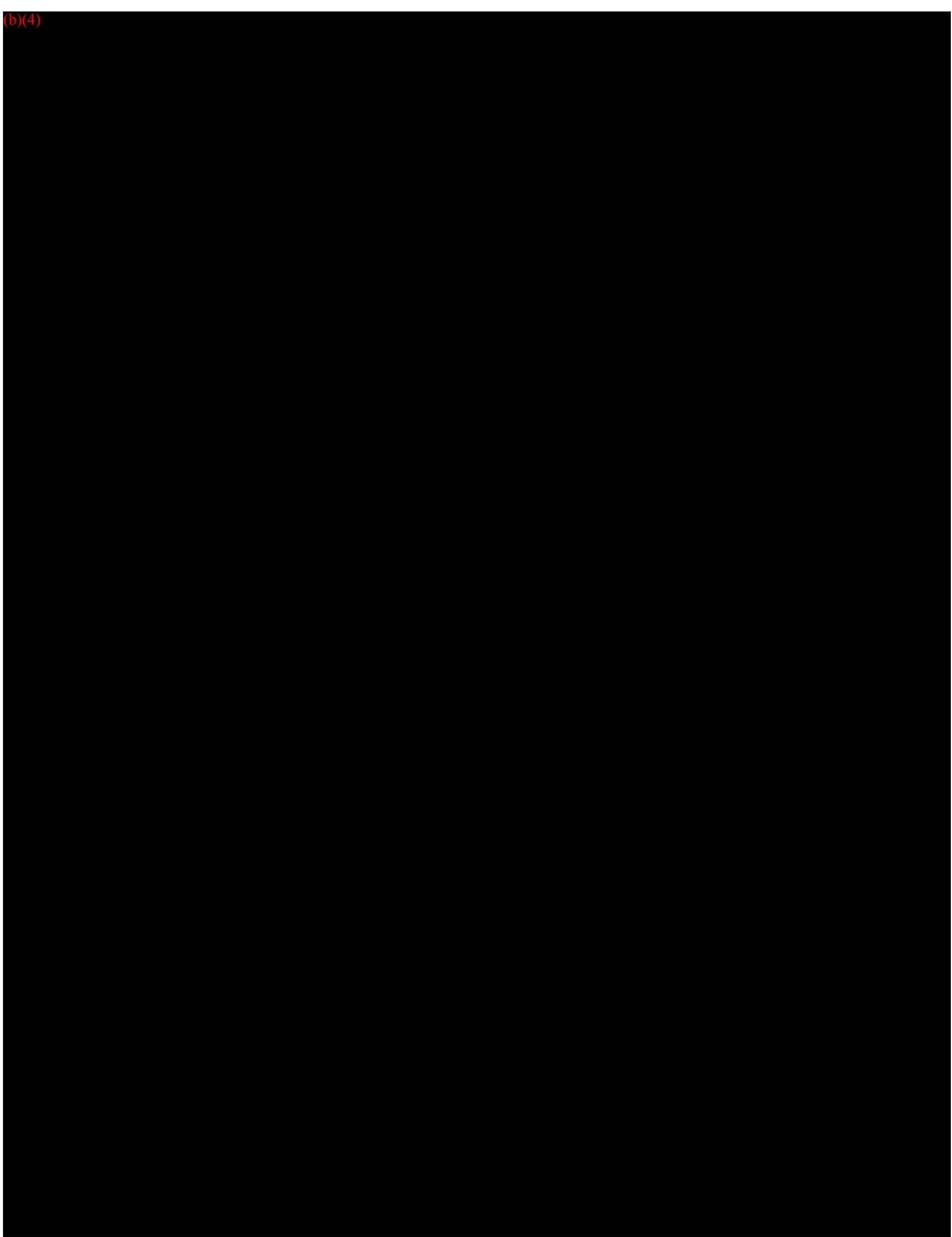


(b) (4)



5v

Pg 24 of 47



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

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/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

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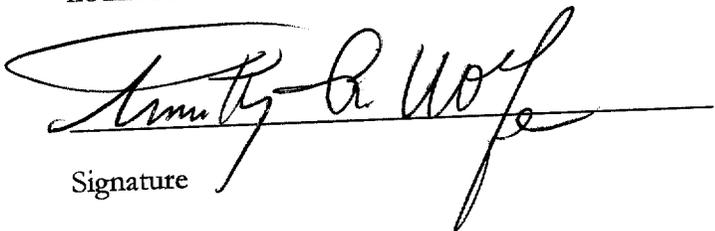
**510(K) NOTIFICATION**

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 807.87(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

RECEIVED  
25 JUL 00 12 20  
FDA/CDRH/OCE/DND

97 AN  
II

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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 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
Establishment Registration Number	1722554
Type	Original - Traditional
Classification Name and Product Code	Applicator, laryngo-tracheal, topical anesthesia 73 CCT
Classification	Class II
Panel	Anesthesiology
Common/Usual Name	Atomizer
Trade Name	Laryngo-tracheal Mucosal Atomization Device (MADgic™™)
Predicate Devices	Astra Disposable Spray Cannula K894755
Performance Standards	None established

**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.

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)

80

## 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.

Component	Material	Material Grade
5cc Syringe	Polypropylene	USP Class VI
Female Luer	Polycarbonate	
Tubing	Polyvinylchloride	
Actuator adapter	Polycarbonate	
Atomizer tip	Polycarbonate	
Wire	Stainless Steel	No patient, user, or fluid path contact.
Adhesive	Cyclohexanone	Medical – Reagent Grade
Adhesive	UV Cured	USP Class VI

**Comparison to Predicate Device**

	WT Laryngo-Tracheal Mucosal Atomization Device	Astra Disposable Spray Cannula
<b>Dosage amount</b>	User controlled	User controlled
<b>Delivery form</b>	Fine particle spray mist	Fine particle spray mist
<b>Cannula shape</b>	Semi-rigid	Semi-rigid
<b>Spray generated by</b>	Piston syringe	Pressurized container
<b>Spray tip diameter</b>	0.157”	0.316”
<b>Materials</b>	Polycarbonate and polyvinylchloride	Polypropylene
<b>Disposable</b>	Yes	Yes

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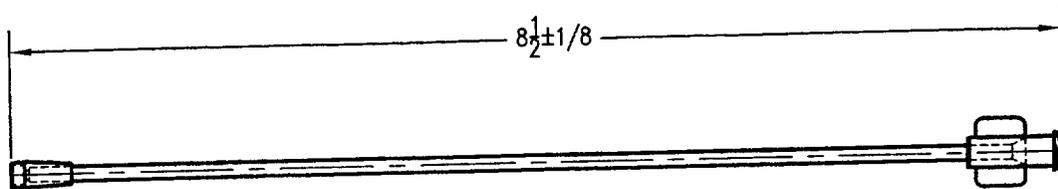


Figure1: Laryngo-Tracheal Mucosal Atomization Device (MADgic™)

### 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.

Single patient  
Use only.

**Rx Only**

Wolfe Tory Medical, Inc.  
Salt Lake City, UT 888-380-9808  
[www.wolfetory.com](http://www.wolfetory.com)

## 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.wolfetory.com](http://www.wolfetory.com)  
P/N 70-xxxx Rev 04/00

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**References:**

1. Kaplan, J.D. and D.P. Schuster, *Physiologic consequences of tracheal intubation*. Clin Chest Med, 1991. 12(3): p. 425-32.
2. Bulow, K., T.G. Nielsen, and J. Lund, *The effect of topical lignocaine on intubating conditions after propofol-alfentanil induction*. Acta Anaesthesiol Scand, 1996. 40(6): p. 752-6.
3. Dyson, D.H., *Efficacy of lidocaine hydrochloride for laryngeal desensitization: a clinical comparison of techniques in the cat*. J Am Vet Med Assoc, 1988. 192(9): p. 1286-8.
4. Mallick, A., S.N. Smith, and A.R. Bodenham, *Local anaesthesia to the airway reduces sedation requirements in patients undergoing artificial ventilation [see comments]*. Br J Anaesth, 1996. 77(6): p. 731-4.
5. McCrirrick, A. and J.A. Pracilio, *Awake intubation: a new technique [see comments]*. Anaesthesia, 1991. 46(8): p. 661-3.
6. Mongan, P.D. and R.D. Culling, *Rapid oral anesthesia for awake intubation*. J Clin Anesth, 1992. 4(2): p. 101-5.
7. Sidhu, V.S., et al., *A technique of awake fiberoptic intubation. Experience in patients with cervical spine disease [see comments]*. Anaesthesia, 1993. 48(10): p. 910-3.
8. Sutherland, A.D. and R.T. Williams, *Cardiovascular responses and lidocaine absorption in fiberoptic- assisted awake intubation*. Anesth Analg, 1986. 65(4): p. 389-91.
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10. Gaumann, D.M., et al., *Effects of topical laryngeal lidocaine on sympathetic response to rigid panendoscopy under general anesthesia*. ORL J Otorhinolaryngol Relat Spec, 1992. 54(1): p. 49-53.
11. Giorgi, L., et al., *[Topical laryngo-tracheal anesthesia and intraocular pressure in anesthesia for ophthalmic surgery]*. Minerva Anestesiol, 1994. 60(1-2): p. 43-7.
12. Konrad, C., et al., *Is an alkalized lignocaine solution a better topical anaesthetic for intratracheal application?* Eur J Anaesthesiol, 1997. 14(6): p. 616-22.
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16. Stoelting, R.K., *Circulatory response to laryngoscopy and tracheal intubation with or without prior oropharyngeal viscous lidocaine*. Anesth Analg, 1977. 56(5): p. 618-21.

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17. Venus, B., V. Polassani, and C.G. Pham, *Effects of aerosolized lidocaine on circulatory responses to laryngoscopy and tracheal intubation*. Crit Care Med, 1984. 12(4): p. 391-4.
18. Yusa, T., et al., [*Effects of intratracheal lidocaine spray on circulatory responses to endotracheal intubation*]. Masui, 1990. 39(10): p. 1325-32.

## **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 Legally Marketed Device	Laryngo-Tracheal Mucosal Atomization Device (MADgic™)
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	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

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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:

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