



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 19, 2016

Teleflex Medical
Kristen Bisanz
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, NC 27560

Re: K153470

Trade/Device Name: MADgic™ Laryngo-Tracheal Mucosal Atomization Device
Regulation Number: 21 CFR 868.5170
Regulation Name: Laryngotracheal Topical Anesthesia Applicator
Regulatory Class: Class II
Product Code: CCT
Dated: July 22, 2016
Received: July 25, 2015

Dear Kristen Bisanz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

James J. Lee

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Digitally signed by James J. Lee -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=James J. Lee -S,
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Date: 2016.08.19 10:10:56 -0400

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153470

Device Name

MADgic Laryngo-Tracheal Mucosal Atomization Device

Indications for Use (Describe)

The MADgic Laryngo-Tracheal Mucosal Atomization Device is intended for the application of topical anesthetics to the oropharynx and upper airway region.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 007 - 510(k) Summary

510(k) SUMMARY**MADgic™ Laryngo-Tracheal Mucosal Atomization Device****Name, Address, Phone and Fax Number of Applicant**

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919.433.4932
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Contact Person

Kristen Bisanz
Regulatory Affairs Specialist

Date Prepared

December 01, 2015

Device Name

Trade Name:	MADgic™ Laryngo-Tracheal Mucosal Atomization Device
Classification Name:	Applicator, Laryngo-Tracheal, Topical Anesthesia
Product Code:	CCT
Regulation Number:	868.5170
Classification:	II
Classification Panel:	Anesthesiology

Predicate Device

This submission demonstrates substantial equivalence to the predicate device MADgic™ Laryngo-Tracheal Mucosal Atomization Device which was cleared in submission K002255.

Device Description

The MADgic™ 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 semi-rigid 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 extensions into the desired position. As the syringe plunger is compressed, the anesthetic is forced into the tubular extension and out of 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

Section 007 - 510(k) Summary

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, and then proceed to the hypopharynx, epiglottis and vocal cords, larynx and trachea via direct visualization using a laryngoscope.

Indications for Use

The MADgic™ Laryngo-Tracheal Mucosal Atomization Device is intended for the application of topical anesthetics to the oropharynx and upper airway region.

Patient Population

This device is for patients requiring topical anesthetic before intubation.

Environments of use

The environments of use are hospitals and sub-acute facilities as directed by a physician.

Contraindications

There are no contraindications for this device.

Substantial Equivalence

The proposed device is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) Number	Date Cleared
MADgic™ Laryngo-Tracheal Mucosal Atomization Device	Wolfe Tory Medical	K002255	September 19, 2000

Section 007 - 510(k) Summary**Comparison to Predicate Device**

The proposed device has the same indications for use, operating principles, classification, function, and general design as the predicate device. Biocompatibility testing and performance testing have been performed on the proposed device in order to establish substantial equivalence to the predicate device. The proposed changes to the device do not impact the safety or effectiveness of the MADgic™ Laryngo-Tracheal Mucosal Atomization Device.

	Predicate K002255 MADgic™ Laryngo- Tracheal Mucosal Atomization Device	Proposed MADgic™ Laryngo-Tracheal Atomization Device	Equivalence
Classification Name	Applicator, Laryngo-Tracheal, Topical Anesthesia	Applicator, Laryngo-Tracheal, Topical Anesthesia	Identical
Device Name	MADgic™ Laryngo-Tracheal Mucosal Atomization Device	MADgic™ Laryngo-Tracheal Mucosal Atomization Device	Identical
Common Name	Atomizer	Atomizer	Identical
Product Code	73CCT	73CCT	Identical
Classification	Class II	Class II	Identical
Regulation Number	868.5170	868.5170	Identical
Indications for Use	The MADgic™ Laryngo-Tracheal Mucosal Atomization Device is intended for the application of topical anesthetics to the oropharynx and upper airway region.	The MADgic™ Laryngo-Tracheal Mucosal Atomization Device is intended for the application of topical anesthetics to the oropharynx and upper airway region.	Identical
Prescription	Yes	Yes	Identical
Environment of Use	Hospitals, Sub-acute facilities, and emergency medical services	Hospitals, Sub-acute facilities, and emergency medical services	Identical
Patient Population	Patients requiring topical anesthesia before intubation	Patients requiring topical anesthesia before intubation	Identical
Contraindications	None	None	Identical
Shelf Life	Three (3) years from date of manufacture	Three (3) years from date of manufacture	Identical
Typical Particle Size	30-100 microns	30-100 microns	Identical

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System Dead Space	MAD600/600OS = 0.25mL MAD700-730/730OS = 0.19mL MAD720 = 0.13mL	MAD600/600OS = 0.24mL MAD700-730/730OS = 0.18mL MAD720 = 0.12mL	Equivalent
Tip Diameter	0.19 inches (4.8mm)	0.19 inches (4.8mm)	Identical
Applicator Length	MAD600/600OS = 8.5 inches (21.6cm) MAD720/730/730OS = 4.5 inches (11.4cm)	MAD600/600OS = 8.9 inches (22.6cm) MAD720/730/730OS = 4.9 inches (12.4cm)	Equivalent
Sterilization	Non-Sterile	Non-Sterile	Identical
Packaging	Packaged individually in polyethylene pouches with twenty-five (25) devices per inner carton, four (4) cartons per case (for a total of 100 devices)	Packaged individually in polyethylene pouches with twenty-five (25) devices per inner carton, four (4) cartons per case (for a total of 100 devices)	Identical
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Identical
Dosage Amount	User Controlled	User Controlled	Identical
Material for Tubing	Alpha Gary 2222R-90	Colorite Polymers Unichem, 9088-015, Clear, DEHP-Free PVC	Equivalent
Material for Luer Adaptor	Polycarbonate	Polyvinyl Chloride 2014 G-010	Equivalent
Material for Wire	302 Stainless Steel	302 Stainless Steel	Identical
Material for Spray Tip	Dow Calibre 2081-15, Polycarbonate	Dow Calibre 2081-15, Polycarbonate	Identical
Material for Spray Tip Insert	Chevron K-Resin, KR03	Chevron K-Resin, KR03	Identical
Material for Syringe	Polypropylene and Non-Latex Rubber	Polypropylene and Non-Latex Rubber	Identical
Material for Adhesive	Cyclohexanone	Cyclohexanone	Identical
Material for Foil Hot Stamp	Not present	100% Virgin, high clarity polyethylene film	Equivalent

Section 007 - 510(k) Summary**Materials**

All patient contacting materials, including those with indirect patient contact, are in compliance with ISO 10993-1. Biocompatibility testing has been performed on the proposed device and meets the acceptance criteria.

Test	Acceptance Criteria	Results
Cytotoxicity - L929 MEM Elution Assay	The test article will meet the requirements of the test if it obtains a Grade of 0,1,or 2 (not more than 50% of the cells are round, devoid of intracytoplasmic granules, and no extensive cell lysis)	Acceptable
Sensitization – Kligman Maximization Assay	The test article will be considered a non-irritant if the difference between the test article mean score and the vehicle control mean score is 1.0 or less.	Acceptable
Irritation – Intracutaneous Injection Assay	The test article will meet the requirements of the test if it receives a Grade of 1, 0 or less using the Kligman scoring system.	Acceptable

Performance Data

Non-clinical performance testing has been conducted in order to support that the proposed device performs as intended and the product conforms to user needs.

Test	Test Objective	Acceptance Criteria	Results
Visual Inspection	To visually inspect the device for defects of components or assembly	Visually observe for: - Proper assembly and presence of all components - No cracks in the tip and luer - No short shots in the molded components - The presence of solvent around circumference of bonding surface covering a minimum of one third of the total area - No gaps between the insert post and tubing	Pass
Flow Test	To validate the flow rate of the device	The flow rate should be greater than or equal to 225 sccm and less than or equal to 700 sccm.	Pass
Leak Test	To validate the leak value of the device	The leak value should be less than or equal to 0.05psi.	Pass
Hydrostatic Test	To validate the effect of hydrostatic pressure on the device	The device must remain assembled after being subjected to a minimum 300psi hydrostatic pressure.	Pass

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Atomization Test Post Hydrostatic	To validate the atomization function of the device	Upon atomization there can be no streaming, no excessive dripping, or occlusions.	Pass
Tensile	To validate the tensile strength of the device	The tensile strength should be greater than or equal to 6.0 lb.	Pass

The testing below summarizes the specification verification.

Test	Specification	Acceptance Criteria
Typical Particle Size	30-100 microns	N/A. Specification Study.
System Dead Space	MAD600/600OS = 0.24mL MAD700-730/730OS = 0.18mL MAD720 = 0.12mL	N/A. Specification Study.
Tip Diameter	0.19 inches (4.8 mm)	N/A. Specification Study.
Applicator Length	MAD600/600OS/700 = 8.9 inches MAD720/730/730OS = 4.9 inches	N/A. Specification Study.
Conical Fittings with 6% Taper	Clauses 4.1-4.1 of ISO 540-2:1998	Certificate of Conformance from the Supplier
Sterile Hypodermic Syringes of Single Use	ISO 7886-1:1993	Certificate of Conformance from the Supplier

Conclusion

Based on the performance and comparative test results, the proposed MADgic™ Laryngo-Tracheal Mucosal Atomization Device is substantially equivalent to the predicate device cleared to market in K002255. The modifications made to the MADgic™ Laryngo-Tracheal Mucosal Atomization Device do not introduce any new issues of safety and effectiveness.