510(k) Summary

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Medica Holdings, LLC
5200 Meadows Rd Ste 150
Lake Oswego, OR 97035

Official Contact: George Reed
President

Proprietary or Trade Name: Medicant Mucosal Atomizer

Common/Usual Name: Laryngotracheal topical anesthesia applicator

Classification Name: 21CFR 868.5170
CCT - Applicator (Laryngo-Tracheal), Topical Anesthesia
Class II

Predicate Device: K153470 - MADgic Laryngo-Tracheal Mucosal Atomization Device

Reference Device: K070596 – Sharn Topical Applicator

Device Description: The proposed device delivers the solution through the nasal passages, directly to the laryngo-tracheal region via a wand-like configuration or the device is placed inside an endotracheal tube for a directed spray. The device is offered in 3 configurations, all supplied with a 3 cc syringe.

Description	With a 3 cc syringe
Nasal cone which is 1.65” long	X
4.5” long tube	X
8.5” long tube	X

Indications for Use: The Medicant Mucosal Atomizer is intended for the application of topical anesthetics to the oropharynx and upper airway region.

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

Environments of Use: Hospitals and clinical settings where topical anesthethic solutions are needed.

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Comparison to the predicate device

Device Comparison	**Proposed Device** Medicant Mucosal Atomizer	**Primary Predicate** MADgic Laryngo-Tracheal Mucosal Atomization Device K153470	**Reference Device** Sharn Topical Applicator K070596
Indicated Use	The Medicant Mucosal Atomizer 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	Intended for atomizing topical anesthetics to the oropharynx and upper airway regions
Patient Population	Individuals requiring topical anesthetics at the direction and discretion of the clinician.	Individuals requiring topical anesthetics at the direction and discretion of the clinician.	Individuals requiring topical anesthetics at the direction and discretion of the clinician.
Environment of Use	Hospitals and clinical settings where topical anesthetic solutions are needed.	Hospitals and clinical settings where topical anesthetic solutions are needed.	Hospitals and clinical settings where topical anesthetic solutions are needed.
Rx	Yes	Yes	Yes
Design	Single Patient Disposable, Non-sterile	Single Patient Disposable, Non-sterile	Single Patient Disposable, Non-sterile
Components	Syringe Flexible tube – 4.5” and 8.5” Atomizer tip / nozzle Nasal cone	Syringe Flexible tube – 4.5” and 8.5” Atomizer tip / nozzle Nasal cone	Syringe Flexible tube Atomizer tip / nozzle
Places inserted	Nasal Orotrachael	Nasal Orotrachael	Nasal Orotrachael
Total Dose Delivered From a 3 ml syringe	2.9 ml saline 2.8 ml lidocaine	2.8 ml saline 2.8 ml lidocaine	unknown
Particle Size MMAD (um)	18.8 um saline 18.7 um lidocaine	18.7 um saline 18.7 um lidocaine	unknown
Plume Geometry	Similar	Similar	unknown
Biocompatibility	Cytotoxicity Sensitization Intracutaneous	Cytotoxicity Sensitization Intracutaneous	Tested to ISO 10993-1
Delivery form	Fine mist spray	Fine mist spray	Fine mist spray

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The Medicant Mucosal Atomizer is viewed as substantially equivalent to the predicate device because:

Indications for Use - The indications for use are similar between both devices.
Discussion - The indications for use are identical for the proposed device and the predicate – MADgic Laryngo-Tracheal Mucosal Atomization Device - K153470.

Patient Population - The patient population for the proposed device and predicate device are different. The predicate narrowed the patient population to patients requiring intubation. However, we have included a reference device – Sharn Topical Applicator – K070596 – which has a similar patient population to the Medicant Mucosal Atomizer.

Discussion - The difference is patient population between the proposed device and the predicate – MADgic Laryngo-Tracheal Mucosal Atomization Device - K153470 – does not raise different questions of safety and effectiveness. The reference device – Sharn Topical Applicator – K070596 – has similar indications for use, patient population, and environment of use.

Environment of Use - The indications for use are similar between both devices.
Discussion - The environment of use are similar for the proposed device and the predicate – MADgic Laryngo-Tracheal Mucosal Atomization Device - K153470.

Technology – The Medicant Mucosal Atomizer delivers the solution through the nasal passages, directly to the laryngo-tracheal region via a wand-like configuration or the device is placed inside an endotracheal tube for a directed spray. The delivery form results in a fine mist spray.
Discussion – The technology is similar for the proposed device as compared to the predicate - MADgic Laryngo-Tracheal Mucosal Atomization Device - K153470.

Non-Clinical Performance Testing Summary –

Non-clinical performance testing included:

- Aerosol Performance and Comparison – Lidocaine and saline
  - Total Dose
  - Particle Size (MMAD – microns)
  - Geometric Standard Deviation (GSD)
- Plume Geometry – lidocaine and saline
  - Spray Distance
  - Velocity
  - Dispersion Angle
- Biocompatibility
- Aging / Shelf-life – post-aging performance
- Mechanical – drop test, bond tensile strength
- ISO 594-1 Luer performance

Biocompatibility of Materials –
The components in patient contact are characterized as similar for the proposed device and the predicate, which is:

- Externally Communicating, Tissue and

- Surface Contact, Mucosa

- Duration of Use – limited (< 24 hours)
- Cytotoxicity, Sensitization, Irritation, Particulate Material, and Toxicology Risk Assessment

Discussion -
The type of materials as well as the type and duration of patient contact is similar for the proposed and predicate device. Testing of the materials in patient contact were found to be non-cytotoxic, non-sensitizers, and a non-irritant.

Substantial Equivalence Conclusion:
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device did not raise different questions of safety or effectiveness for the intended use when compared with the predicate and can be considered as substantially equivalent to the predicate device.