Trudell Medical International
Marianne Tanton
Director, Quality and Regulatory Affairs
725 Baransway Drive
London, Ontario N5V 5G4
Canada

Re: K203400
Trade/Device Name: Corrugated tube with mouthpiece accessory
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 20, 2021
Received: May 21, 2021

Dear Marianne Tanton:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brandon Blakely, PhD
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203400

Device Name
Corrugated tube with mouthpiece accessory

Indications for Use *(Describe)*
The corrugated tube is an accessory to the MC 300 ® Nebulizer. It is designed to work in conjunction with the MC 300 ® Nebulizer to extend the patient interface away from the nebulizer. The accessory is a single patient use device that is intended to be used with either mouthpiece or mask for pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician.

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 5 – 510(k) Summary

Prepared: 14 June 2021

1. Submitter

Trudell Medical International
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Contact: Marianne Tanton
Director, Quality and Regulatory Affairs
Phone: 1-519-455-7060
Email: mtanton@trudellmed.com

2. Device Name

Trade Name:	None
Common Name:	Corrugated tube with mouthpiece accessory
Classification Name:	Nebulizer 21 CFR 868.5630
Regulatory Class:	II
Product Code:	CAF

3. Predicate Device

MC300* Nebulizer - K173367
Trudell Medical International

The predicate device has not been subject to a recall.

4. Device Description and Principle of Operation

The corrugated tube with mouthpiece accessory is designed to work in conjunction with the cleared predicate device, MC300 * Nebulizer (K173367) to extend the patient interface away from the nebulizer.

In line with FDA's definition of a "medical device accessory", the corrugated tube with mouthpiece accessory is intended to supplement the performance of the parent device, MC300* Nebulizer (K173367).

The principle of operation of MC300 Nebulizer remains the same as cleared under K173367.*

5. Indications for Use

The corrugated tube is an accessory to the ***MC 300*** ® Nebulizer. It is designed to work in conjunction with the ***MC 300*** ® Nebulizer to extend the patient interface away from the nebulizer. The accessory is a single patient use device that is intended to be used with either

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mouthpiece or mask for pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician.

The MC300 Nebulizer indications for use remains the same as cleared under K173367*.

6. Comparison to predicate device

The predicate device, MC300* Nebulizer (K173667) and the subject device (corrugated tube with mouthpiece) used with MC300* Nebulizer, are identical in purpose, function, core technology and method of operation.

The purpose of this submission is the addition of corrugated tube with mouthpiece accessory for use with the predicate device, MC300* Nebulizer (K173367). Table 1 provides a comparison of the subject and predicate devices.

Table 1: Comparison to Predicate Device

Element of Comparison	**Corrugated tube with mouthpiece** to be used with MC300* Nebulizer (Subject Device)	**MC300* Nebulizer** K173367 (Predicate Device)	**Comparison**
Indications for Use	*The nebulizer indications for use remains the same as cleared under K173367*. The corrugated tube is an accessory to the MC 300 ® Nebulizer. It is designed to work in conjunction with the MC 300 ® Nebulizer to extend the patient interface away from the nebulizer. The accessory is a single patient use device that is intended to be used with either mouthpiece or mask for pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician.	The nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician. The device is designed to aerosolize prescribed medication for inhalation by a patient in the hospital, clinic or home care environment. The nebulizer is a single patient use device.	Supplement
Principle of Operation	*The nebulizer's principle of operation remains the same as cleared under K173367*.	Pneumatic Jet Nebulizer	Supplement

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Element of Comparison	**Corrugated tube with mouthpiece** to be used with MC300* Nebulizer (Subject Device)	**MC300* Nebulizer** K173367 (Predicate Device)	Comparison
	The corrugated tube with mouthpiece is an accessory to the MC300* Nebulizer. It is designed to work in conjunction with the MC300* Nebulizer to extend the patient interface away from the nebulizer.		
Environment of use	Hospital, Clinic or Home		Similar
Patient population	Adult and pediatric patients (ages 2 years and above)		Similar
Single Patient Use	Yes		Similar
Aerosolization	Continuous during inhalation and exhalation		Similar
Type of device	Disposable, single patient use, prescription only, non-sterile		Similar
Manufacturing process	Plastic molding		Similar

Note: Type of gas source, flow rates and maximum fill volume are nebulizer characteristics and are not listed in the comparison table.

7. Performance Data

7.1. Aerosol Characterization

Aerosol characterization testing was performed in accordance with relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH – 1993). The test results demonstrated substantially equivalent in-vitro performance between the subject device (corrugated tube with mouthpiece or mask) used with MC300* Nebulizer, and the predicate device, MC300* Nebulizer (K173367). The results of the testing are summarized in Tables 2 to 4 below.

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Table 2. Summary of Aerosol Characterization Test Results for Corrugated Tube with Mouthpiece (Subject Device) Used with MC300* Nebulizer and MC300* Nebulizer (K173367) (Predicate Device) at 8 L/min

Metric	Albuterol Sulfate		Budesonide		Ipratropium Bromide	
	Subject Device	Predicate Device	Subject Device	Predicate Device	Subject Device	Predicate Device
Total Mass (µg)	1248.8±57.8	1409.0±84.5	403.6±54.6	381.2±21.4	535.3±28.2	583.2±17.1
Fine Particle Fraction (0.98-5.39µm aerodynamic diameter) (%)	70.5±1.1	69.1±1.9	53.6±8.2	58.9±4.5	70.3±0.9	70.7±1.8
Fine Particle Mass (µg)	905.7±51.9	974.4±76.7	212.9±9.9	223.9±14.5	376.6±22.1	412.7±17.2
MMAD (µm)	2.9	2.9	5.0	4.6	3.4	3.1
GSD	2.2	2.2	1.7	1.8	2.2	2.1

Table 3. Summary of Aerosol Characterization Test Results for Corrugated Tube with Mouthpiece (Subject Device) Used with MC300* Nebulizer and MC300* Nebulizer (K173367) (Predicate Device) at 13 psi (4 L/min)

Metric	Albuterol Sulfate		Budesonide		Ipratropium Bromide	
	Subject Device	Predicate Device	Subject Device	Predicate Device	Subject Device	Predicate Device
Total Mass (µg)	1394.4±121.8	1348.8±158.9	358.1±16.5	383.3±21.8	513.3±40.3	555.4±35.8
Fine Particle Fraction (0.98-5.39µm aerodynamic diameter) (%)	71.6±3.5	72.0±2.5	59.5±3.9	59.4±7.0	74.4±1.1	72.1±2.4
Fine Particle Mass (µg)	995.9±67.0	971.3±124.8	213.0±16.5	227.8±22.8	381.8±28.2	400.8±32.2
MMAD (µm)	2.8	2.4	4.7	4.6	2.4	2.9
GSD	2.2	2.2	1.7	1.9	2.2	1.9

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Table 4. Summary of Aerosol Characterization Test Results for MC300* Nebulizer with Supine Accessory with Mask (Subject Device with Mask) and MC300* Nebulizer with Mask (Predicate Device with Mask) at 8 L/min

Metric	Albuterol Sulfate		Budesonide		Ipratropium Bromide	
	Subject Device with mask	Predicate Device with mask	Subject Device with mask	Predicate Device with mask	Subject Device with mask	Predicate Device with mask
Total Mass (µg)	1396.7±124.7	1435.4±92.2	356.3±13.0	333.5±22.8	607.9±33.5	570.5±29.8
Fine Particle Fraction (0.98-5.39µm aerodynamic diameter) (%)	71.5±1.3	69.5±2.1	64.2±1.7	61.3±7.1	73.4±1.4	70.3±1.9
Fine Particle Mass (µg)	999.7±103.9	997.5±72.5	228.8±9.6	203.6±16.6	446.1±26.0	401.3±21.2
MMAD (µm)	2.6	2.8	4.3	4.5	2.6	3.1
GSD	2.2	2.2	1.8	1.8	2.1	2.0

7.2. Biocompatibility Testing

Biological endpoints applicable to the corrugated tube with mouthpiece accessory are listed below. Materials were tested in accordance with ISO 10993-1 (2018) and the results satisfied the requirements. All in vitro and in vivo studies were performed and included the following battery of tests: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Genotoxicity, Extractables/Leachables, and Chemical Characterization with a Biological Risk Assessment.

Table 5. Summary of Biocompatibility Testing Conducted

ISO Standard	Test/ Assessment
10993-1	Biological Risk Assessment
10993-5	Cytotoxicity Study Using the ISO Elution Method
10993-3	Genotoxicity: Bacterial Reverse Mutation Study
10993-3	Genotoxicity: Mouse Lymphoma Assay
10993-11	Acute Systemic Toxicity Study in Mice

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ISO Standard	Test/ Assessment
10993-10	Intracutaneous Study in Rabbits
10993-10	Guinea Pig Maximization Sensitization
10993-17	Establishment of allowable limits for leachable substances
10993-12	Solvent and Extraction Condition Verification for ISO 10993-18 Chemical Characterization Program
10993-18	Chemical characterization of materials

7.3. Dry Gas Pathway Testing

To support the safe use of the corrugated tube with mouthpiece accessory in dry gas conditions, a worst-case assessment of volatile organic compounds (VOCs) and fine particles (particulate matter PM2.5) was conducted. Testing results and risk assessment demonstrated that exposure during use of the corrugated tube with mouthpiece accessory is unlikely to result in toxicological effects.

8. Clinical Performance Summary

Not applicable. The determination of substantial equivalence is not based on Clinical Performance data.

9. Conclusion

The non-clinical data demonstrate that the use of the corrugated tube with mouthpiece accessory used with MC300* Nebulizer (K173367) is safe and effective for use in patients for the delivery of aerosolized inhalation medications and is therefore substantially equivalent to the predicate device, MC300* Nebulizer, cleared under K173367.