August 24, 2023

Monaghan Medical Corporation
℅ Joseph Azary
Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K220145
Trade/Device Name: Monaghan medical filtered mouthpiece kit
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH, CAF
Dated: August 24, 2023
Received: August 24, 2023

Dear Joseph Azary:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220145

Device Name
Monaghan Medical Filtered Mouthpiece Kit

Indications for Use *(Describe)*
The filter kit is intended for single patient use as an accessory to a small volume nebulizer. The device can be used in a hospital, home, or clinic environment with patients 5 years and above to minimize the amount of medical aerosol exhaled into the air.

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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510(k) Summary
FILTERED MOUTHPIECE

1. SUBMITTER/510(K) HOLDER

Monaghan Medical Corporation
153 Industrial Boulevard
Plattsburgh, NY 12901

Contact Name: Joseph Azary (Aztech Regulatory & Quality LLC)
Email: jazary@erols.com
Telephone: (203) 242-6670

Updated: August 17, 2023

2. DEVICE NAME

Proprietary Name:	None
Common/Usual Name:	Mouthpiece / Exhalation Filter
Classification Name:	Nebulizer (Direct Patient Interface)
Classification Regulation:	21 CFR 868.5630
Product code:	CAF
Classification:	Class 2
Medical Specialty (Panel):	Anesthesiology

3. PREDICATE DEVICES

Primary Predicate Device

- ***Salter Nebulizer Exhalation Aerosol Filter*** / Nebutech (Salter / Sunmed) – K983403

Secondary Predicate Device

- ***AeroEclipse®*** Durable BAN™ nebulizer (Trudell Medical International) – K080926

Reference

- The filter used in the subject device is identical to the filter in the Heat and Moisture Exchanger and Filter, which was cleared under 510(k) K132709

4. DEVICE DESCRIPTION AND PRINCIPLE OF OPERATION

The Filtered Mouthpiece is an accessory to the ***AeroEclipse®*** BAN™ nebulizer. The filtered mouthpiece kit will be sold as a stand-alone filter kit or as part of a kit with the ***AeroEclipse®*** BAN™ nebulizer. The replacement filters can be purchased in bulk pack.

The device is a tube with a port to a check valve and a filter element. On inhalation the flow is straight through the tube from the nebulizer to the patient with a check valve preventing air from the filter exhaust from backflowing and diluting the delivered aerosol. On exhalation the check valve opens and all flow is directed through a filter to capture exhaled aerosol particles. This minimizes fugitive emissions from therapies such a methacholine challenge test or the delivery of antibiotics.

In line with FDA's definition of a "medical device accessory" the Filtered Mouthpiece is intended to supplement the performance of the parent device, AeroEclipse® Durable BAN™ nebulizer (K080926).

The principle of operation of the Filtered Mouthpiece with nebulizer remains the same as the cleared AeroEclipse® Durable BAN™ nebulizer.

Another Nebulizer that includes a filter has been identified and is listed as the primary predicate.

The filter consists of a plastic body, which incorporates a mechanical filter pad (Synthetic Fibers and Foam) and connectors (male / female).

5. INTENDED USE

The filter kit is intended for single patient use as an accessory to a small volume nebulizer. The device can be used in a hospital, home or clinic with patients 5 years and above to minimize the amount of medical aerosol exhaled into the air.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device is to be used as an accessory to the ***AeroEclipse®*** Durable BAN™ nebulizer (K080926). The ***AeroEclipse®*** Durable BAN™ Nebulizer is provided with a mouthpiece. The subject device is composed of identical materials as the mouthpiece provided with the predicate device, except that it contains a filter and exhaust connector. The filter materials used in the subject device are identical the reference device subject to 510(k) K132709.

The subject device has similar / equivalent properties as the primary predicate device including a) Use Environment, b) Rx Only, c) Non-Sterile, d) Single Patient Use, e) Similar Medical Grade Polymers, f) Filter Material, Filter Rating and Type, g) Filter Efficiency VFE and BFE, and h) Intended use to be used with nebulizer to minimize the amount of medical aerosol exhaled into the air.

The differences include a) primary predicate does not have a reuse claim and b) the primary predicate has a smaller size filter area. These differences in technology for the device raise no new questions of safety and effectiveness. Testing data demonstrates these technological characteristics are substantially equivalent to the predicate device.

Characteristic	**Monaghan Medical Corporation** **Filtered Mouthpiece**	**Salter Nebulizer Exhalation Aerosol Filter** **Aka Nebutech (K983403)**	**Trudell Medical International** **AeroEclipse® Durable BAN™ Nebulizer (K080926)**
Intended Use	Used with a nebulizer to reduce emissions	Used with a nebulizer to reduce emissions	Administer aerosolized medication
Indications for Use (partial excerpt)	The filter kit is intended for single patient use as an accessory to a small volume nebulizer. The device can be used in a hospital, home or clinic with patients 5 years and above to provide filtration to minimize the amount of medical aerosol exhaled into the air.	Indicated for use whenever the physician or healthcare professional administering or prescribing medical aerosol products to a patient with a Salter Labs nebulizer wishes to minimize the amount of medical aerosol exhaled into the air.	The AeroEclipse® Durable BAN™ Nebulizer is a single patient reusable device, intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication prescribed by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.
Use Environment	Home, Hospitals or Clinics	Home, Hospitals or Clinics	Home, Hospitals or Clinics

Used with Nebulizer	Used with small volume nebulizer	Used with Nebulizer (Salter – Nebutech)	Not Applicable
Prescription	Rx only	Rx only	Rx only
Sterility	Non-Sterile	Non-Sterile	Non-Sterile
Single Patient Use	Yes	Yes	Yes
Reusable	Yes (for single patient)	No reuse claims	Yes (for single patient)
Materials	Medical Grade Polymers (Polypropylene) Filter (identical materials to K132709)	Medical Grade Polymers (Polypropylene, Polystyrene)	Medical Grade Polymers (Polypropylene)
Disposable	Yes Disposable	Yes Disposable	Yes Disposable
Filter Media Area	Approx 6360 mm^2	>3871 mm^2	No Filter
Filter Type	Hydrophobic	Hydrophobic	No Filter
Mouthpiece	Yes	Yes	Yes
Filter Rating	0.3um filtration	0.3um filtration	No Filter
Filter Efficiency	99.999% BFE 99.99% VFE	99.99% BFE 99.99% VFE	No filter
Valve for Filter	One Way Valve Mouthpiece	One Way Valve Mouthpiece	Not Applicable
Connector Size	22mm conical connector.	20mm connector	22mm conical connector.

7. PERFORMANCE TESTING

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 (filtered mouthpiece) used with AeroEclipse® Durable BAN™ nebulizer, and the predicate device, AeroEclipse® Durable BAN™ nebulizer (K080926).

7.2 Biocompatibility Testing

Biological endpoints applicable to the filtered 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, Pyrogenicity. Acute Systemic Toxicity, Genotoxicity, Chemical Characterization with a Biological Risk Assessment.

Table 1. Summary of Biocompatibility Testing Conducted

ISO Standard	Test/ Assessment
10993-1	Biological Risk Assessment
10993-5	Cytotoxicity Study Using the ISO Elution Method
10993-5	Cytotoxicity Study Using the ISO Elution Method (After Cidex exposure / high level disinfection)
10993-3	Genotoxicity: Bacterial Reverse Mutation Study
10993-10	Intracutaneous Study in Rabbits
10993-10	Guinea Pig Maximization Sensitization
10993-11	Acute Systemic Toxicity Study in Mice
10993-11	Pyrogenicity in Rabbits
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 filtered 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 filtered mouthpiece accessory is unlikely to result in toxicological effects.

7.4 Filter Efficiency

The Filtered Mouthpiece was independently tested and meets the Bacterial Filtration Efficiency (BFE) of 99.999% and Virus Filtration Efficiency (VFE) of 99.99% were confirmed.

8. CLINICAL PERFORMANCE SUMMARY

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

9. CONCLUSION

Based upon the non-clinical data it has been demonstrated that the proposed device compared to the predicates can be found to be substantially equivalent. The subject device does not raise new issues of safety or effectiveness compared to the predicate devices.