December 19, 2024

Medline Industries, LP.
Nicole Schaffer
Regulatory Affairs Manager
Three Lakes Drive
Northfield, Illinois 60093

Re: K241778
Trade/Device Name: Hudson RCI Comfort Flo® CubCannula™
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: June 20, 2024
Received: November 20, 2024

Dear Nicole Schaffer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241778

Device Name
Hudson RCI Comfort Flo® CubCannula™

Indications for Use *(Describe)*
The Hudson RCI Comfort Flo® CubCannula™ is a single use nasal cannula intended to administer respiratory gas to a spontaneously breathing patient through both nostrils delivering flow rates ranging from 1 to 25 LPM.

CubCannula™ is a patient interface used to deliver heated and humidified gas to the following populations:
• Neonates, birth to 1 month of age
• Infants, 1 month to 2 years of age
• Children, 2 to 12 years of age

CubCannula™ is designed for use in professional healthcare environments and must be prescribed by a physician.

CubCannula is used in conjunction with the Humidification System intended to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

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510(k) Summary
K241778

Submitter / 510(k) Sponsor
Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Submission Correspondent
Nicole Schaffer
Regulatory Affairs Manager
nschaffer@medline.com

Summary Preparation Date
December 19, 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Hudson RCI Comfort Flo® CubCannula™
Classification Name: Respiratory Gas Humidifier
Product Code: BTT
Classification Panel: Anesthesiology (Respiratory)
Regulatory Class: Class II
Regulation Number: 21 CFR 868.5450
Common/Usual Name: Nasal Cannula

Predicate Device
F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range
K222197

Device Description
The Comfort Flo® CubCannula™ is a single patient use nasal cannula containing two-prongs intended to administer gas to a spontaneously breathing patient through both nostrils. CubCannula™ is a patient interface used as a conduit to deliver heated and humidified gas to the following pediatric sub-populations: neonates, infants, children. The nasal cannula incorporates soft prongs, a soft, silicone, kink and crush resistant lariat, in addition to a color-coded bolo for easy size identification. The CubCannula™ nasal cannulas will be available in five sizes: Extra Small (XS), Small (S), Medium (M), Large (L), and Extra Large (XL). The nasal cannula will be secured to the patient's face via use of Hydrocolloid pads (CubPads™) to assist with easy positioning and change out of the cannula during use.

The following table lists the Hudson RCI Comfort Flo® CubCannula™ and CubPad™ model numbers and configurations.

The CubCannula™ will be individually packaged with a pair (2) of CubPads™. CubPad™ replacements will be available in a separate package.

Table 3-1: Configurations

Model Number	Description
HUD2701XS	Cub Cannula – Extra Small
HUD2701S	Cub Cannula – Small
HUD2701M	Cub Cannula – Medium
HUD2701L	Cub Cannula – Large
HUD2701XL	Cub Cannula – Extra Large
HUD2702	Cub Cannula Replacement Pads – Small (CubPads Small)
HUD2703	Cub Cannula Replacement Pads – Large (CubPads Large)

Indications for Use

The Hudson RCI Comfort Flo® CubCannula™ is a single use nasal cannula intended to administer respiratory gas to a spontaneously breathing patient through both nostrils delivering flow rates ranging from 1 to 25 LPM.

CubCannula™ is a patient interface used to deliver heated and humidified gas to the following populations:
- Neonates, birth to 1 month of age
- Infants, 1 month to 2 years of age
- Children, 2 to 12 years of age

CubCannula™ is designed for use in professional healthcare environments and must be prescribed by a physician. CubCannula is used in conjunction with the Humidification System intended to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.

Patient Population
- Neonates, birth to 1 month of age
- Infants, 1 month to 2 years of age
- Children, 2 to 12 years of age

Contraindications

This therapy must not be used where continuous positive airway pressure (CPAP) is contraindicated. This includes:
- Non-spontaneous breathing.
- Injury, congenital abnormalities and anatomical malformations where bi-nasal prongs or physical conditions where positive airway pressure is contraindicated, including but not limited to: pneumothorax, pneumocephalus, cerebrospinal fluid leak, and hypotension.
- Injury/trauma/severe deformity that might be exacerbated by use of nasal prongs or mask.

Environments of Use
- Professional healthcare environment

Table 3-2: Comparison of Subject vs. Predicate

Device Characteristic	Proposed Device Comfort Flo® CubCannula™	Primary Predicate Device F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range K222197	Comparison Analysis
Manufacturer	Medline Industries	Fisher & Paykel Healthcare Ltd	
Product Code	BTT	BTT	Identical
Regulation Number	868.5450	868.5450	Identical
Indications for Use	The Hudson RCI Comfort Flo® CubCannula™ is a single use nasal cannula intended to administer respiratory gas to a spontaneously breathing patient through both nostrils delivering flow rates ranging from 1 to 25 LPM. CubCannula™ is a patient interface used to deliver heated and humidified gas to the following populations: • Neonates, birth to 1 month of age • Infants, 1 month to 2 years of age • Children, 2 to 12 years of age CubCannula™ is designed for use in professional healthcare environments and must be prescribed by a physician. CubCannula is used in conjunction with the Humidification System intended to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.	The Fisher & Paykel Healthcare Optiflow Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients. This product is designed for use in hospital environments and must be prescribed by a physician. The intended pediatric subpopulations targeted for use of the F&P Optiflow Junior 2 Nasal Cannula range includes: • Neonates, birth up to 1 month of age • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age	Similar. The indications for use for the subject and predicate device are similar with the exception the environment of use. The predicate is cleared for use in hospital environments only, while the subject device is seeking clearance in professional healthcare environments.
Shelf Life	2 years	3 years	Similar. The subject device has a shelf life of 2 years while the predicate has a shelf life of 3 years.
Useful Life	10 days	7 days	Similar. The subject device has a maximum useful life of 10 days while the predicate device has a maximum useful life of 7 days. Testing has been performed to validate the 10-day useful life (safety

			factor included).
Prescription vs. OTC	Prescription	Prescription	Identical
Contraindications	This therapy must not be used where continuous positive airway pressure (CPAP) is contraindicated. This includes: • Non-spontaneous breathing. • Injury, congenital abnormalities and anatomical malformations where bi-nasal prongs or physical conditions where positive airway pressure is contraindicated, including but not limited to: pneumothorax, pneumocephalus, cerebrospinal fluid leak, and hypotension. • Injury/trauma/severe deformity that might be exacerbated by use of nasal prongs or mask.	This therapy must not be used where continuous positive airway pressure (CPAP) is contraindicated. This includes: • Non-spontaneous breathing. • Injury, congenital abnormalities and anatomical malformations where bi-nasal prongs or physical conditions where positive airway pressure is contraindicated, including but not limited to: pneumothorax, pneumocephalus, cerebrospinal fluid leak, and hypotension. • Injury/trauma/severe deformity that might be exacerbated by use of nasal prongs or mask.	Identical
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	Identical
Single Use vs. Reusable	Single Use	Single Use	Identical
Patient Population	• Neonates, birth to 1 month of age • Infants, 1 month to 2 years of age • Children, 2 to 12 years of age	• Neonates, birth to 1 month of age • Infants, 1 month to 2 years of age • Children, 2 to 12 years of age	Identical
Patient Acuity	Spontaneously breathing patients	Spontaneously breathing patients	Identical
Operating Environment	Professional Healthcare	Hospital environment	Identical
Ambient Operating Temperature	20-26°C	18 – 26 °C	Similar. The ambient temperatures of both the CubCannula and the predicate device are nearly identical. The maximum temperature range is identical to the predicate. The minimum value does not extend beyond the approved limits of the predicate device. As the ambient temperature of the

<table>
<tr><td></td><td></td><td></td><td>subject device is within that of the predicate, this does not raise and additional concerns for safety and effectiveness of the subject device.</td></tr>
<tr><td>Range of Cannula Sizes</td><td>Available in five different sizes which are indicated by color.</td><td>Available in six different sizes which are indicated by color</td><td>Similar. The subject device includes the same sizes as the predicate (Extra Small, Small, Medium, Large, Extra Large) with the exception of the Extra Extra Large size. The exclusion of this additional size offered with the predicate device does not raise any additional concerns of safety and effectiveness for the subject device.</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Flow Rates</td><td>
<table>
<tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr>
<tr><td>HUD2701XS</td><td>XS</td><td>1-8</td></tr>
<tr><td>HUD2701S</td><td>S</td><td>1-8</td></tr>
<tr><td>HUD2701M</td><td>M</td><td>1-8</td></tr>
<tr><td>HUD2701L</td><td>L</td><td>1-25</td></tr>
<tr><td>HUD2701XL</td><td>XL</td><td>1-25</td></tr>
</table>
</td><td>
<table>
<tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr>
<tr><td>OJR410</td><td>XS</td><td>0.5-8</td></tr>
<tr><td>OJR412</td><td>S</td><td>0.5-9</td></tr>
<tr><td>OJR414</td><td>M</td><td>0.5-10</td></tr>
<tr><td>OJR416</td><td>L</td><td>0.5-23</td></tr>
<tr><td>OJR418</td><td>XL</td><td>0.5-25</td></tr>
<tr><td>OJR520</td><td>XXL</td><td>1-36</td></tr>
</table>
</td><td>Similar. The flowrates of both the CubCannula and the predicate device are nearly identical. All five allowable flowrate ranges fall within the allowable flow ranges of the predicate device. No values extend beyond the cleared limits of the predicate device.</td></tr>
</table>

Summary of Non-Clinical Testing

Testing was conducted to demonstrate substantial equivalence of Hudson RCI Comfort Flo® CubCannula™ to the predicate, F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range (K222197). A summary of testing is presented below with more information provided in the applicable sections.

Biocompatibility Testing

The Comfort Flo® CubCannula was tested for biocompatibility using a combination of ISO 10993-1:2018 and ISO 18562-1:2017 methodologies. All biological endpoint testing including cytotoxicity, sensitization, irritation, acute systemic toxicity, and genotoxicity revealed passing results. The extractables/leachables testing on the humidified gas pathway components revealed MOS values greater than 1.0 after clinically relevant considerations and condensate attenuation. VOC and Particulates testing indicated that the CubCannula emissions are well below the health-based thresholds for both volatile organic compounds and particulates. Based upon these results in conjunction with the ISO 10993-1:2018 testing, the CubCannula referenced in this document is biocompatible and does not present a foreseen biological and/or toxicological risk to those patient populations the device is intended for.

The following tests were performed to evaluate the biocompatibility of CubCannula:

- ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-5: 2009 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993:10: 2010 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic
- Toxicity
- ISO 10993-6:2016– Tests for local effects after implantation
- ISO 10993-3:2014– Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-12:2012, Biological evaluation of medical devices – Part 12: Sample preparation and reference material
- ISO 10993-17:2002, Biological evaluation of medical devices – Part 17: Establishment of
- allowable limits for leachable substances
- ISO 10993-18:2005 - Biological evaluation of medical devices – Part 18: Chemical Characterization of Materials
- ISO 18562-1:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare
- applications, Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare
- applications, Part 3: Tests for emissions of volatile organic compounds (VOCs)

Performance Testing (Bench)

The following tests were performed on CubCannula and CubPads:

- Post aging Visual Inspection
- Relevant Humidity Output testing
- Thermal Overshoot testing
- Connection strength testing following selected pre-conditioning
- Flow Leak Test/ Gas path leak testing
- Shelf Life Testing
- Useful Life Testing

- Peel Testing
- Transportation simulation
- ISO gauging

Performance Testing (Bench) Standards:

- ISO 5356-1:2015, Anesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.
- ISO 80601-2-74:2017 Medical electrical equipment- Part 2-74: Particular requirements for basic safety and essential performance of respiratory devices
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Medline Industries, LP concludes that the Hudson RCI Comfort Flo® CubCannula™ are substantially equivalent to the predicate based on patient population, intended use, comparison of their technological characteristics and performance. In addition, the conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the legally marketed predicate device.