July 2, 2025

Medline Industries, LP.
Sirisha Kommana
Sr. Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K250312
Trade/Device Name: Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant; Hudson RCI® Comfort Flo Plus Cannula Extra Small
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: June 4, 2025
Received: June 4, 2025

Dear Sirisha Kommana:

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,

John S. Bender -S
2025.07.02 15:23:20 -04'00'

for 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.

Submission Number *(if known)*

K250312

Device Name

Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant;
Hudson RCI® Comfort Flo Plus Cannula and Comfort Flo® Soft Plus Cannulas Extra Small

Indications for Use *(Describe)*

Hudson RCI® Comfort Flo Nasal Cannulas Premature, Infant:
Hudson RCI® Comfort Flo Nasal Cannulas Premature, Infant are intended to be used in conjunction with the Comfort Flo Humidification System to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.

It is indicated for single use by premature and infant (birth to 2 years) patients in professional healthcare environments.

Hudson RCI® Comfort Flo® Plus Cannulas and Comfort Flo® Soft Plus Cannulas Extra Small:
Hudson RCI® Comfort Flo® Plus Cannulas and Comfort Flo® Soft Plus Cannulas Extra Small are intended to be used in conjunction with the Humidification System to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.

It is indicated for single use by adult and pediatric (12 years and above) patients in professional healthcare environments.

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.

510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

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

Registration Number: 1417592

Contact Person
Contact Person: Sirisha Kommana, Senior Regulatory Affairs Specialist
Email: SKommana@medline.com
Phone: 724-640-9680

Summary Preparation Date
June 03, 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small
Common Name: Nasal Cannula
Classification Name: Respiratory Gas Humidifier
Product Code: BTT
Classification Panel: Anesthesiology
Regulatory Class: Class II
Regulation Number: 21 CFR 868.5450

Predicate Device
Primary Predicate: F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range (K222197)
Reference Device: F&P Optiflow 3S Nasal Cannula (K191818)

Device Description

Hudson RCI® Comfort Flo Nasal Cannulas Premature, Infant

Comfort Flo nasal cannulas are intended to be used in conjunction with the Comfort Flo Humidification System to provide a continuous flow of heated humidified air to spontaneously breathing patients. Sizes available include adult, pediatric, infant, and premature. This submission includes premature and infant sizes.

Hudson RCI® Comfort Flo Plus Cannulas Extra Small

Cannula tube is assembled with other components to create a product named Comfort Flo® Plus Cannula with/ without Chin Strap. The Comfort Flo Plus cannulas are intended to be used in conjunction with the Humidification system intended to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients. It allows for the safe and effective delivery of heated, humidified oxygen therapy to the patients.

The Comfort Flo Plus Cannulas are available in extra small, small, medium and large configurations. This submission includes extra small size.

Hudson RCI® Comfort Flo Soft Plus Cannulas Extra Small

Comfort Flo Soft Plus cannulas are the same as Comfort Flo Plus cannulas except for head strap. These have a soft/cushioned head strap for patient comfort.

It is used as an alternative to oxygen face mask and allows the patient to continue to talk, eat and drink while receiving the therapy.

This submission includes Hudson RCI® Comfort Flo Soft Plus cannula extra small.

Indications for Use

Hudson RCI® Comfort Flo Nasal Cannulas Premature, Infant:

Hudson RCI® Comfort Flo nasal cannulas Premature, Infant are intended to be used in conjunction with the Comfort Flo Humidification System to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.

It is indicated for single use by premature and infant (birth to 2 years) patients in professional healthcare environments.

Hudson RCI® Comfort Flo® Plus cannulas and Comfort Flo® Soft Plus cannulas Extra Small: Hudson RCI® Comfort Flo® Plus cannulas and Comfort Flo® Soft Plus cannulas Extra Small are intended to be used in conjunction with the Humidification System to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients.

It is indicated for single use by adult and pediatric (12 years and above) patients in professional healthcare environments.

Contraindications

None

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device K222197	Reference Device K191818	Comparison Analysis
Product Name	Hudson RCI® Comfort Flo Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small	F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range	F&P Optiflow 3S Nasal Cannula	N/A
510(k) Reference	TBD	K222197	K191818	N/A
Product Owner	Medline Industries, LP	Fisher and Paykal	Fisher and Paykal	N/A
Product Code	BTT	BTT	BTT	Same
Regulation Number	868.5450	868.5450	868.5450	Same
Classification Name	Respiratory gas humidifier (accessory to)	Respiratory gas humidifier	Respiratory gas humidifier (accessory to)	Same
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Same
Intended Use/Indications for use	**Hudson RCI® Comfort Flo nasal cannulas Premature,**	**F&P Optiflow Junior 2**	The F&P Optiflow™ 3S nasal cannula is a	Same

	Infant are intended to be used in conjunction with the Comfort Flo Humidification System to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients. It is indicated for single use by premature and infant (birth to 2 years of age) patients in professional healthcare environments. **Hudson RCI® Comfort Flo® Plus cannulas and Comfort Flo® Soft Plus cannulas Extra Small** are intended to be used in conjunction with the Humidification System to provide a continuous flow of heated and humidified air/oxygen mixtures to spontaneously breathing patients. It is indicated for single use by adult and pediatric (12 years and above) patients in professional healthcare environments.	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	14-day single use nasal cannula interface for use with specified respiratory gas humidifiers to deliver Nasal High Flow (NHF) therapy to spontaneously breathing adult patients. This product is designed to be used by appropriately qualified healthcare professionals in a hospital / institutional environment.	Although the wording is not identical to predicate's indications for use as seen on 510k summary the proposed device and the predicate device have the same overall indicated use, of providing a continuous flow of heated and humidified air to spontaneously breathing patients. Hudson RCI® Comfort Flo nasal cannulas Premature, Infant are indicated for single use by pediatric population from birth to 2years. The proposed device (Hudson RCI® Comfort Flo® Plus cannulas Extra Small) has additional pediatric patient

		• Children, 2 years up to 12 years of age **F&P Optiflow Junior 2+** 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 subpopulation targeted for use on the F&P Optiflow Junior 2+ Nasal Cannula includes:		population to accommodate patient population above 12 years of age. The proposed devices (Hudson RCI® Comfort Flo® Plus cannulas Extra Small) are also indicated for use in adult patient population, which is equivalent to the reference device (K191818).

		• Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age **F&P Optiflow Junior 2 HM Cannula**: The Fisher & Paykel Healthcare Optiflow™ Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients. This product is designed for use in long term care environments and must be prescribed by a physician. The intended pediatric subpopulation targeted for use on the F&P Optiflow		

		Junior 2 Nasal Cannula includes: • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age **F&P Optiflow Junior 2+ HM Cannula:** The Fisher & Paykel Healthcare Optiflow™ Junior 2+ nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients. This product is designed for use in long term care environments and must be prescribed by a physician. The intended pediatric subpopulation targeted for use on		

		the F&P Optiflow Junior 2+ Nasal Cannula includes: • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age		
Patient Population	Comfort Flo Nasal Cannulas Premature, Infant: Premature, Infant patients (birth to 2 years) Comfort Flo Plus Cannulas Extra Small: Adult and pediatric patients (12 years and above)	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	Adults	Similar The proposed device, Comfort Flo Nasal Cannula Premature, Infant and the predicate device is intended for pediatric populations birth to 2 years of age. The proposed device, Hudson RCI® Comfort Flo Plus Cannula Extra Small is indicated for additional patient population to accommodate for pediatric population (12 years and above).

				The proposed devices, Comfort Flo Plus Cannula Extra Small are indicated for adult patient population which is equivalent to the reference device (K191818).
Patient Acuity	Spontaneously breathing patients	Spontaneously breathing patients	Spontaneously breathing patients	Same
Prescription vs. OTC	Prescription Use (Rx) only	Prescription Use (Rx) only	Prescription Use (Rx) only	Same
Operating Environment	Professional Healthcare environment	Hospital environment and long-term care environments	Hospital environment	Same Professional healthcare environment includes hospital and long-term care environments
System Specifications	When set to Comfort Flo Humidification System Recommended Flow Rates: Hudson RCI® Comfort Flo Cannula Premature, Infant: 1-8 LPM Hudson RCI® Comfort Flo Plus Cannula	When the Airvo 2 system is set to Junior mode OJR416, OJR416HM (Large) 2 – 20 L/min OJR418, OJR418HM (Extra Large) 2 – 25 L/min When the Airvo 2 system is set to Default mode: OJR520, OJR520HM	AIRVO / AIRVO 2 Humidifier with 900PT56x-series tube; or tube and chamber kit (e.g. 900PT561) Flow Range: OPT1042 (Small) 10 - 50L/min OPT1044 (Medium) 10 - 60 L/min	Similar The upper range of flow rate of pediatric population of 20LPM is same as the predicate device. The lower range of flow rate of pediatric population of proposed device

	Extra Small 1-60 LPM	(XXL) 10 – 50 L/min When the MR850 is set to invasive mode OJR410 (Extra small) 0.5-8 L/min OJR412 (Small) 0.5-9 L/min OJR414 (Medium) 0.5-10 L/min OJR416 (Large) 0.5 – 23 L/min OJR418 (Large) 0.5 – 25 L/min OJR418, OJR520 (Double Extra Large) 1 – 35 L/min	OPT1046 (Large) 10 - 60 L/min	is validated to 1LPM The upper range of flow rate of adult population is covered in the reference device (K191818).
Single Use vs. Reusable	Single Use only	Single Use only	Single Use only	Same
Useful Life	30 days	7 days	< 14 days	The proposed device claims a 30 day useful life
Shelf-Life	5 Years	3 Years	3 Years	The proposed device claims a 5 year shelf life
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Dispose of according to hospital protocol	Same

Summary of Non-Clinical Testing

Testing was conducted to demonstrate substantial equivalence of Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small, 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 biocompatibility evaluation for Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small was conducted in accordance with ISO 10993-1:2018 *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process*, as recognized by FDA.

The patient contacting materials of Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small that contact the patient and the humidified gas have been characterized as external communicating (indirect gas pathway), tissue/bone/dentin communicating with a potential for permanent contact (>30 days) due to cumulative use and surface device intact skin contacting, with a potential for permanent (>30 days) contact due to cumulative use. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2009 Annex A.

The following tests were performed to evaluate the biocompatibility of Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small

- 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 Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small.

- Post aging Visual Inspection
- Relevant Humidity Output testing
- Thermal Overshoot testing
- Gas path and headgear joint and connection strength testing following selected pre-conditioning intended to simulate worst case life scenarios.
- Flow Leak Test/ Gas path leak testing
- Head Gear Testing
- Shelf Life Testing
- Useful Life Testing
- Transportation simulation
- ISO gauging

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.

Other Testing

NA

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 Nasal Cannula Premature, Infant and Hudson RCI® Comfort Flo Plus Cannula Extra Small are as safe and as effective for their intended use as the predicate device F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range (K222197).