June 27, 2023

Medline Industries, Inc
% Joy Gutermuth
Senior Specialist (Consultant)
Rqm+
2790 Mosside Blvd.
Suite 800
Monroeville, Pennsylvania 15146

Re: K223100
Trade/Device Name: Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater (050-14)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: June 13, 2023
Received: June 13, 2023

Dear Joy Gutermuth:

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
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OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
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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.

Submission Number *(if known)*

K223100

Device Name

Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater (050-14)

Indications for Use *(Describe)*

The Hudson RCI AQUATHERM® III Plus External Adjustable Electronic Heater is designed for use with the Hudson RCI Nebulizer Adaptor and the AQUAPAK® system to provide continuous heated aerosol for respiratory applications.

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

DATE PREPARED
June 26, 2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Hudson RCI AquaTherm III Plus External Adjustable Electronic Heather ("AquaTherm Heater")
Common Name:	Nebulizer Heater
Regulation Number:	868.5630
Class:	II
Product Code:	CAF
Premarket Review:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1)
Review Panel:	Anesthesiology

PREDICATE DEVICE IDENTIFICATION
The AquaTherm Heater is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K880473	Aero-Mist Nebulizer Heater/ Pegasus Research Corporation	✓

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The AquaTherm devices are adjustable output temperature heaters. The AquaTherm Heater is placed between a nebulizer adaptor and a reservoir of sterile solution. When a gas flow is initiated to the nebulizer, sterile solution is drawn up from the reservoir and through the stainless-steel puncture pin in the center of the AquaTherm Heater. The solution is heated as it flows through the pin. The heated solution is then drawn into the nebulizer adaptor where it is aerosolized into the patient gas stream.

INDICATIONS FOR USE
The Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater is designed for use with the Hudson RCI Nebulizer Adaptor and the AquaPak system to provide continuous heated aerosol for respiratory applications.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
Medline Industries believes that the AquaTherm Heater is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, and uses similar or identical materials as the device cleared in K880473. The subject device has the same intended use and similar technological characteristics to the device cleared in K880473. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

Product Features	**Proposed** **Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater**	**Predicate** **Pegasus Research Corporation Aero-Mist Nebulizer Heater**
Device Description	The AquaTherm devices are adjustable output temperature heaters. The AquaTherm Heater is placed between a nebulizer adaptor and a reservoir of sterile solution. When a gas flow is initiated to the nebulizer, sterile solution is drawn up from the reservoir and through the stainless-steel puncture pin in the center of the AquaTherm Heater. The solution is heated as it flows through the pin. The heated solution is then drawn into the nebulizer adaptor where it is aerosolized into the patient gas stream.	The heater warms and evaporates particles impinging on the heater disc which is disposed below the nebulizer. Return water drains through the center tube into the sterile water supply container below the heater. The water is drawn up from the sterile water supply by a draw tube which is part of the nebulizer itself. The draw tube passes through the center tube of the heater in use.
Intended Use	To provide continuous heated aerosol for respiratory applications.	"… to provide warm aerosol of water particles into the respiratory tract."* *Intended use not clearly stated in 510(k) summary
Indications for Use	The Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater is designed for	"Respiratory therapy, in hospital, to provide warm aerosol of water particles into the respiratory tract."*

Product Features	**Proposed** **Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater**	**Predicate** **Pegasus Research Corporation Aero-Mist Nebulizer Heater**
	use with the Hudson RCI Nebulizer Adaptor and the AquaPak system to provide continuous heated aerosol for respiratory applications.	*Indications for use not clearly stated in 510(k) summary
Representative Image* ***images feature nebulizer adaptors and tubing which are not included within this submission.**		
Classification	Class II	Class II
Product Code	CAF	CAF
Regulation Number	§868.5630	§868.5630
Regulation Name	Nebulizer	Nebulizer
Accessories	• Aquapak Nebulizer adapter • Aquapak prefilled nebulizer reservoir Sold separately and not part of this submission	• Nebulizer adapter • Prefilled nebulizer reservoir Sold separately
Environment	Hospital	Hospital
Sterilization Method	Non-sterile	Non-sterile
Patient Contacting Materials	Indirect patient contact only: Stainless steel	Unknown- 510(k) does not describe patient-contacting materials

Product Features	**Proposed** **Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater**	**Predicate** **Pegasus Research Corporation Aero-Mist Nebulizer Heater**
Principles of Operation	Adjustable temperature. The AquaTherm Heater is placed between a nebulizer adaptor (not included) and a reservoir of sterile solution (not included). When a gas flow is initiated to the nebulizer, sterile solution is drawn up from the reservoir and through the stainless-steel puncture pin in the center of the AquaTherm Heater. The solution is heated as it flows through the pin. The heated solution is then drawn into the nebulizer adaptor where it is aerosolized into the patient gas stream. Rainout is returned to the reservoir via the nebulizer adapter return tube (rainout return tube is part of the nebulizer adapter, not the subject device).	Adjustable temperature. Warms and evaporates particles on the heater disc below the nebulizer. Return water drains through the center tube into the container below the heater. The water is drawn up from the water supply by a draw tube; the nebulizer draw tube passes through the center tube of the heater.
Power Supply	Mains powered	Mains powered
Voltage and Power	115 VAC at 60Hz, 1.5 A	115 VAC (+/- 10 volts) 1.7 A
Storage and Transportation Environment	Temperature: -20 °C to 50 °C Relative Humidity: 0% to 94% (non-condensing)	Temperature: -40 °C to 70 °C Relative Humidity: 10% to 100% (including condensate)
Output Temperature Range	25°C -37°C	25°C -40°C
Heat up Time	25 minutes (about 20 minutes after each subsequent temperature adjustment)	Approximately 20 minutes
Operating Environment	• Temperature: 18°C to 26°C • Relative Humidity: 30% to 75% (non-condensing) • Pressure: 700 to 1060 hPa	• Temperature: 10°C to 40°C • Relative Humidity: 30% to 75% (non-condensing) • Pressure: 700 to 1060 hPa

Product Features	**Proposed** **Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater**	**Predicate** **Pegasus Research Corporation Aero-Mist Nebulizer Heater**
Biocompatibility	• External communicating, limited contact device that indirectly contacts tissue/bone/dentin. • Indirect gas pathway	Unknown- 510(k) does not describe any biocompatibility.
Standards Utilized	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 18562-1 ISO 18562-2 ISO 18562-3 IEC 60601-1-2 IEC 60601-1-11	UL544
Non-Clinical Testing	Packaging Cleaning process EMC testing	Unknown- 510(k) does not state testing.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the AquaTherm Heater. The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility
- Packaging
- Cleaning
- EMC Testing

The results of these tests indicate that the AquaTherm Heater is substantially equivalent to the predicate devices.

CONCLUSION

Based on the testing performed, including gas pathway biocompatibility testing, and compliance to the latest edition of IEC 60601-1-2, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed AquaTherm Heater are assessed to be substantially equivalent to the predicate devices.