DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 26, 2016

Teleflex Medical, Inc.
Brian Gall
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K153010
Trade/Device Name: Hudson RCI® AquaPak® Sterile Prefilled Nebulizers
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: June 16, 2016
Received: June 17, 2016

Dear Mr. Brian Gall:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
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Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153010

Device Name
Hudson RCI® AquaPak® Sterile Prefilled Nebulizers

Indications for Use *(Describe)*

The Hudson RCI® AquaPak® Sterile Prefilled Nebulizer adds sterile water or saline solution in aerosol form to a patient's breathing gases. It may be used with pediatric (ages 2 years and above) and adult 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.

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Section 31 – Updated 510(k) Summary

510(k) SUMMARY

K153010 – Hudson RCI® AquaPak® Sterile Prefilled Nebulizers

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd.
Morrisville, NC 27560 USA
Phone: 919-228-4350
Fax: 919-361-3939

B. Contact Person

Brian Gall
Senior Regulatory Affairs Specialist, Respiratory Division

C. Date Prepared

15 June 2016

D. Device Name

Trade Name: **Hudson RCI® AquaPak® Sterile Prefilled Nebulizers**

Common Name: Nebulizer

Classification Name: Nebulizer (Direct Patient Interface), CFR – 868.5630, Class II

E. Device Description

Hudson RCI® AquaPak® Sterile Prefilled Nebulizers provide sterile water or sterile saline for inhalation therapy. Nebulizers generate aerosol, a fine mist of liquid water (or sodium chloride solution) that is suspended in the gas to be inhaled by the patient during aerosol therapy.

The **Hudson RCI® AquaPak® Sterile Prefilled Nebulizers** consist of two components, a sterile adaptor and a prefilled sterile reservoir. The adaptor may be type 028 or type 033. The standard model with a yellow collar (type 028) and the quiet model with a blue collar (type 033) feature an adjustable air entrainment window, which provides a specific oxygen concentration by entraining room air into the oxygen stream. Prefilled sterile reservoirs for the **Hudson RCI® AquaPak® Sterile Prefilled Nebulizers** come in three sizes; 440ml, 760ml and 1070ml, and may be sterile water or sterile sodium chloride solution. The sterile reservoirs are cleared under K141214, and are presented here for reference only. Each reservoir, when combined with an adaptor component, provides nebulizer functionality when connected to a gas source.

The primary purpose of this Traditional 510(k) submission is to change the nebulizer adaptor cleared in K141214 from non-sterile to sterile, and update the packaging materials and shelf life to maintain sterility.

F. Indications for Use

The **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** adds sterile water or saline solution in aerosol form to a patient's breathing gases. It may be used with pediatric (ages 2 years and above) and adult patients.

G. Target Population

The **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** may be used with pediatric (ages 2 years and above) and adult patients.

H. Environments of Use

This device is intended for hospital, sub-acute facilities, long-term care facilities, and in a home care environment.

This product is single use only.

I. Contraindications

There are no known contraindications.

J. Comparative Characteristics

The proposed **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** is substantially equivalent to the nebulizer in the predicate device:

Comparative Characteristics	**Proposed Device: Hudson RCI® AquaPak® Sterile Prefilled Nebulizer**	**Predicate Device: Hudson RCI® AquaPak® Prefilled Nebulizer**
Manufacturer	**Teleflex Medical, Inc.**	**Same**
510(k) Number	**K153010**	**K141214**
Indications for Use	**The Hudson RCI® AquaPak® Sterile Prefilled Nebulizer adds sterile water or saline solution in aerosol form to a patient's breathing gases. It may be used with pediatric (ages 2 years and above) and adult patients.**	**Same**
Principle of Operation	**Jet nebulizer with adjustable air entrainment**	**Same**
Gas source	**50 Psi oxygen regulated via a flow meter**	**Same**
Flow rate and	**028 Model:**	**Same**

FiO2 Control Capabilities	**28% at 5 LPM** **35% at 8 LPM** **40% - 98% at 10 LPM** **033 Model:** **33% - 35% at 8 LPM** **40% - 98% at 10 LPM**	
Aerosol Particle Size Delivery	**1.5 to 3 micron range**	**Same**
Sterilization	**Adaptor sterilized by Gamma Sterilization**	**Non-sterile adaptor**
Single Use	**Single Use only device**	**Same**
Shelf Life	**Adaptor – 5 years from date of manufacture**	**Adaptor – N/A**
Packaging	**Adaptors – 50/case, 10 or 20/case when packaged with water/ saline**	**Same**

K. Non-clinical Comparative Performance Testing

Bench testing has been performed to verify that the performance of the proposed **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** is substantially equivalent to the predicate device, and that the **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** will perform as intended.

There are no new patient contacting materials, so no biocompatibility testing was required for this submission.

The 'Lift Pressure', 'Oxygen Entrainment', 'Nebulization Rate', and 'Particle Size Distribution' testing is identical to the testing performed in the predicate K141214. The results of this testing showed that the subject device met all of the acceptance criteria established by the predicate. The 'Packaging configuration / Shelf Life' and 'Sterility Testing' ensure the sterile packaging and sterility are maintained after sterilization and shelf life testing per the referenced standards. The packaging for the subject device met the acceptance criteria of the standards cited below.

Test Performed	Reference to Standard (if applicable)	Principle of Test
Packaging Configuration / Shelf life Testing	ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. ASTM F2096, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Establishes integrity of the package materials and sterile barrier after shelf life testing, visual inspections and nebulization function test. The packaging passed all of the acceptance criteria for the tests.
Sterility Testing	ISO 11137-1:2006 Sterilization of health care products Radiation Part 1: Requirements for development, validation and routine control of a	Validates the correct dose of gamma radiation to ensure a sterile product at the point of use when manufactured, stored, and handled according to the instructions for use.

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	sterilization process for medical devices ISO 11137-2:2013 (third edition) Sterilization of health care products – Radiation Part 2: Establishing the sterilization dose	The packaging passed all of the acceptance criteria for the tests.
Lift Pressure	N/A	Measures the amount of negative pressure required to pull liquid up for nebulization. The device passed all of the acceptance criteria for the tests.
Oxygen Entrainment	N/A	Measures the percentage of oxygen/air mixture when adjusted to preset oxygen percentage. The device passed all of the acceptance criteria for the tests.
Nebulization Rate	N/A	Determines the basic rate at which the liquid is aerosolized and emitted in mL/min. The device passed all of the acceptance criteria for the tests.
Particle Size Distribution	N/A	Determines the particle size (MMAD) and geometric standard deviation (GSD) of the aerosolized liquid. The device was comparable to the predicate.

L. Substantial Equivalence

The proposed **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** is substantially equivalent in intended use, design, performance and principles of operation to the identified predicate device cleared under 510(k) K141214. The differences between the proposed **Hudson RCI® AquaPak® Sterile Prefilled Nebulizer** and the predicate device are minor and raise no new issues of safety and efficacy.