DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 29, 2015

Teleflex Medical, Inc.
James A. Cochie
Sr. Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K142153
Trade/Device Name: Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: II
Product Code: CAF
Dated: March 30, 2015
Received: April 1, 2015

Dear Mr. Cochie:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
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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)*
K142153

Device Name

Hudson RCI® Addipak® Unit Dose Vial, 0.9% Full Normal Saline Solution

Indications for Use *(Describe)*

The Hudson RCI® Addipak® Unit Dose Vial, 0.9% Full Normal Saline Solution may be used in conjunction with a non-ventilatory nebulizer for lavage therapy, or for tracheal irrigation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 25 – 510(k) Summary

510(k) SUMMARY

Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution

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

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8083
Fax: 919-433-4996

B. Contact Person

James Cochie
Sr. Regulatory Affairs Specialist

C. Date Prepared

July 25, 2014 (Revised April 28, 2015)

D. Device Name

Trade Name:	Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution
Common Name:	Saline Solution for Inhalation
Classification Name:	Nebulizer (Direct Patient Interface) CFR – 868.5630, Class II

E. Device Description

Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution is a pre-filled vial of sterile 0.9% saline for inhalation therapy. The content of this product is a 0.90% sodium chloride solution *(normal saline)*. Vials are factory-sealed, made of translucent, color-coded polyethylene, and are available in three sizes (3mL, 5mL, and 15mL). These products are single-use, disposable, and intended for inhalation only.

Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution filled with sterile saline solutions conforms to the specifications of the USP monograph for Sodium Chloride Inhalation Solution.

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Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution have a perforated, break-away twist cap for dispensing the solution. When twisted by the user, the cap breaks away and opens a small hole for solution to pass through. The Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution are designed with inverted graduations to allow the clinician to read volume while dispensing the solution.

F. Indications for Use

The Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution may be used in conjunction with a non-ventilatory nebulizer for lavage therapy, or for tracheal irrigation.

G. Target Population

This device is intended for use on any patient requiring lavage therapy or tracheal irrigation.

H. Environments of Use

This device is intended for home, hospital, and sub-acute facilities.

This product is single use only.

I. Contraindications

There are no known contraindications.

J. Comparative Equivalence Characteristics

The proposed Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution is substantially equivalent to the predicate devices:

Comparative Characteristics	Proposed Device, Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution	Predicate Device, Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution	Predicate Device, Nephron Pharmaceuticals, Sodium Chloride Solution USP, 0.9%
Manufacturer	Teleflex Medical, Inc.	Teleflex Medical, Inc.	Nephron Pharmaceuticals
510(k) Number	K142153	Pre-amendment	K113033
Indications for Use	The Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline may be used in conjunction with a	The Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline may be used in	Sterile, single use device is intended to be used as an accessory to medicinal

	non-ventilatory nebulizer for lavage therapy, or for tracheal irrigation.	conjunction with a non-ventilatory nebulizer for lavage therapy, or tracheal irrigation	nonventilatory nebulizers for respiratory therapy or for tracheal irrigation or lavage therapy
Prescription	Yes	Yes	Yes
Environment of Use	Home, hospital, sub-acute facilities	Home, hospital, sub-acute facilities	Home, hospital, sub-acute facilities
Patient Population	Any patient requiring lavage therapy or tracheal irrigation	Any patient requiring lavage therapy or tracheal irrigation	Same
Contraindications	None	None	None
Materials in Fluid Contact	Vial LDPE – DuPont DPE-20 and Dow HEALTH+ 692	Vial LDPE – DuPont DPE-20 and Celanese EVA 7110	Vial LDPE
Solutions	0.90% Saline Inhalation Solution, USP: 3ml, 5ml, 15ml	0.90% Saline Inhalation Solution, USP: 3ml, 5ml, 15ml	0.9% Saline Inhalation Solution, USP: 3ml, 5ml
Vial Design	Pinched seam between vial and cap for opening	Pinched seam between vial and cap for opening	Pinched seam between vial and cap for opening
	Nozzle opening design to keep contents within when inverted	Nozzle opening design to keep contents within when inverted	Nozzle opening design to keep contents within when inverted
	Raised inverted graduations	Raised inverted graduations	Raised inverted graduations
Manufacturing Process	Per USP monograph	Per USP monograph	Per USP monograph
	Blow-Fill-Seal aseptic process	Blow-Fill-Seal aseptic process	Blow-Fill-Seal aseptic process
Sterilization	Per USP <71>	Per USP <71>	Per USP <71>
Single Use	Yes	Yes	Yes
Shelf Life	2 years from date of manufacture	2 years from date of manufacture	Unknown
Packaging	3ml and 5ml vials packaged 100/box, 10 boxes/case 15ml vials packaged 48/box, 3 boxes/case	3ml and 5ml vials packaged 100/box, 10 boxes/case 15ml vials packaged 48/box, 3 boxes/case	3ml and 5ml vials packaged 100/box or 30 individually wrapped and bar-coded vials

K. Non-clinical Comparative Performance Testing

Bench testing has been performed to verify that the performance of the proposed Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution is substantially equivalent to the predicate devices, and that the Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution will perform as intended.

Section 25 – 510(k) Summary

Test Performed	Reference to Standard (if applicable)	Principle of Test
Leak Test	N/A	Leak detection in polyethylene vial by vacuum method
Twist-Off Test	N/A	A manual removal of the twist-off cap to ensure proper dispensing of solution when inverted and squeezed
Ship Test	ISTA 1A	Shipping simulation to ensure vials are damage-free and do not leak

All patient contacting materials are in compliance with ISO 10993-1. Testing included cytotoxicity, irritation, sensitization, genotoxicity and implantation testing.

In addition, the vial material was tested to USP <661> physiochemical test for plastics and found to meet the criteria for nonvolatile residue, heavy metals and buffering capacity.

L. Substantial Equivalence

The proposed Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution is substantially equivalent in intended use for lavage therapy and tracheal irrigation, design, performance and principles of operation to the identified predicate devices. The differences between the Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution and the predicate devices are minor and raise no new issues of safety and efficacy. The Hudson RCI® AddiPak® Unit Dose Vial, 0.9% Full Normal Saline Solution are substantially equivalent to the currently marketed predicate device.