July 1, 2019

Teleflex Medical, Inc
Sirisha Kommana
Regulatory Affairs Specialist
3015 Carrington Mill Blvd, Suite 600 North
Morrisville, North Carolina 27560

Re: K182847
Trade/Device Name: Hudson RCI® Voldyne® Volumetric Exerciser
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: May 22, 2019
Received: May 23, 2019

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 (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,

for James J. Lee, PhD
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182847

Device Name
Hudson RCI® Voldyne® Volumetric Exerciser

Indications for Use *(Describe)*

The Hudson RCI Voldyne Volumetric Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 yrs) patients. It is a single patient, multi-use device used in hospital or home care setting.

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.

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510(k) SUMMARY
(K182847)

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

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560
Phone: 919-433-4831
Fax: 919-361-3939

B. Contact Person

Sirisha Kommana
Regulatory Affairs Specialist, Respiratory Division

C. Date Prepared

July 1, 2019

D. Device Name

Trade Name:	Hudson RCI® Voldyne® Volumetric Exerciser
Common Name:	Incentive Spirometer
Product Code:	BWF
Regulation Number:	868.5690
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

This submission demonstrates substantial equivalence to Besmed Volumetric Incentive Spirometer (K141355).

F. Device Description

The Hudson RCI® Voldyne® Volumetric Exerciser ("Voldyne") is a volumetric incentive spirometer. It is a single patient multi-use device. The primary interface of the user with the device is through a mouthpiece.

The device contains two chambers; one for the flow chip, and one for the piston. The piston chamber is marked with a graduation from 500 ml to 4,000 ml (for the Voldyne 4000) or 250 ml to 2,500 ml (for the Voldyne 2500 and Voldyne Pediatric) on the front and the back of the main housing. The flow chip chamber for the device is marked with a happy face symbol with arrows pointing to the optimum position of the flow chip. The Voldyne Pediatric version includes a sticker sheet with clouds and trees graphics, which can be placed onto the device.

When the patient inhales the flow chip and piston rise due to the negative pressure created; this indicates breathing volume and flow, while the device provides an exercise incentive to patients who require sustained maximal inspiration (SMI).

G. Indications for Use

The Hudson RCI Voldyne Volumetric Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 yrs) patients. It is a single patient, multi-use device used in hospital or home care setting.

H. Contraindications

None

I. Substantial Equivalence

The proposed device is substantially equivalent to the predicate device.

Comparison of Predicate vs. Proposed Device

Features	Teleflex Medical Hudson RCI® Voldyne® Volumetric Exerciser (K182847)	Besmed Volumetric Incentive Spirometer (Predicate Device-K141355)
Classification Name	Spirometer, Therapeutic (Incentive)	Spirometer, Therapeutic (Incentive)
Product Code	BWF	BWF
Class	II	II
Regulation Number	868.5690	868.5690
Single Patient use only	Yes	Yes
Usability	Multi-use	Multi-use
Patient Population	Adults and Pediatric patients (above 5 years)	Patients requiring inspiratory exercise
Prescription Only	Yes	Yes
Environments of use	Home care settings and hospitals	Home care settings and hospitals
Volume	2500 and 4000 cc	2500 and 5000 cc
Sterile	No	No
Indication for Use	The Hudson RCI Voldyne Volumetric Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 yrs) patients. It is a single patient, multi-use device used in hospital or home care setting.	The Besmed Volumetric Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.
Contraindications	None	None
Basic Components	Housing 1 ball / piston Tubing Mouthpiece	Housing 1 ball / piston Tubing Mouthpiece

Patient Interface	Mouthpiece	Mouthpiece
Materials Evaluation	The materials used in the construction of Voldyne were evaluated per ISO 10993-1:2009	The materials used in the construction of predicate were evaluated per ISO 10993-1:2009
Shelf-life	1 Year	Not specified
Accuracy	Equivalent	± 15%
Performance Testing	Age testing (Pre and Post Aging) • Mouthpiece and Tubing Engagement Test • Tubing and Housing Engagement Test • Collapsible Tubing Leakage Test • Volume Accuracy Test • Flow Chip and Piston Operation • Slide Operation	Age Testing -Pre and post-exposure

J. Comparison to the Predicate

The basic technological and operating principles are the same for both devices. Both the predicate and subject device have similar indications for use. Both the subject and predicate device are intended for similar patient populations. Both the subject and predicate device are intended to be used in home care and hospital settings. Both the subject and predicate devices are disposable, non-sterile, single patient use devices. The proposed Voldyne® Volumetric Exerciser is substantially equivalent to the predicate device.

K. Performance Data

Teleflex performed a number of tests to demonstrate that the Voldyne® Volumetric Exerciser meets its performance specifications and that it is substantially equivalent to the predicate Besmed Volumetric Incentive Spirometer (K141355).

The following tests were performed on the proposed devices:

- Shelf Life
- Cleaning validation
- ISO 5356-1:2015- Anaesthetic and respiratory equipment -- Conical connectors -Part 1: Cones and sockets, applicable sections

- Biocompatibility: The Hudson RCI® Voldyne® Volumetric Exerciser is an externally communicating tissue contact, limited duration device (≤24 hours).
  - ISO 10993-1:2009 – 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

The proposed devices were tested to the requirements of ISO 5356-1:2015. Cytotoxicity, Sensitization, Irritation and Systemic Toxicity were performed to demonstrate biocompatibility of the patient contacting materials to the requirements of ISO 10993-1:2009. Overall, the results are comparable to the predicate and support a determination of substantial equivalence.

L. Conclusion

The Voldyne® Volumetric Exerciser has similar indication for use and technological characteristics as its predicate. The device data and test results demonstrate that the device meets the applicable standards for Voldyne® Volumetric Exerciser and is substantially equivalent to the predicate device.