October 25, 2022

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

Re: K220565
Trade/Device Name: Hudson RCI Triflo II Incentive Deep Breathing Exerciser
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: October 25, 2022
Received: October 25, 2022

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220565

Device Name
Hudson RCI Triflo II Incentive Deep Breathing Exerciser

Indications for Use *(Describe)*
The Hudson RCI Triflo II Incentive Deep Breathing Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 years) patients.

Intended for single-patient, multi-use in a 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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510K SUMMARY

510(k) SUMMARY

Hudson RCI Triflo II Incentive Deep Breathing Exerciser

I. Submitter

Medline Industries, Inc.
1 Three Lake Dr.
Northfield, IL 60093

Phone: 724-640-9680

Contact Person: Nicole Schaffer
Date Prepared: October 25, 2022

II. Device

Name of Device: Hudson RCI Triflo II Incentive Deep Breathing Exerciser
Common or Usual Name: Incentive Spirometer
Classification Name: Spirometer, Therapeutic (Incentive)
Regulatory Class: II
Regulation: 868.5690
Product Code: BWF

III. Predicate Device

Besmed TriBall Incentive Spirometer, K133873

IV. Description of Device

The Hudson RCI Triflo II Incentive Deep Breathing Exerciser. The device is a non-diagnostic, therapeutic spirometer (inspiratory deep-breathing exerciser) designed for a maximum flow rate of approximately 1200 cc/sec. It is supplied in clean, sanitary condition, ready for use. It is designed for single patient use and discarded when no longer needed by the patient to whom assigned. By sequentially lifting the balls that are inside every chamber it provides an exercise incentive to patients who require sustained maximal inspiration (SMI), or similar maneuvers.

V. Indications for Use

The Hudson RCI Triflo II Incentive Deep Breathing Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 years) patients.

Intended for single-patient, multi-use in a hospital or home care setting.

VI. Comparison of the Technological Characteristics with the Predicate Device

510(k) Substantial Equivalence Summary of Key Attributes

Product Features	Proposed Hudson RCI Triflo II Incentive Deep Breathing Exerciser	Predicate Besmed Incentive Spirometer (K133873)	Reference Hudson RCI Voldyne (K182847)	Assessment of Equivalence
Classification	Class II	Class II	Class II	Same
Product Code	BWF	BWF	BWF	Same
Regulation Number	§868.5690	§868.5690	§868.5690	Same
Regulation Name	Incentive Spirometer	Incentive Spirometer	Incentive Spirometer	Same
Indications for Use	The Hudson RCI Triflo II Incentive Deep Breathing Exerciser is intended as an inspiratory deep breathing positive exerciser for adult and pediatric (above 5 years) patients. Intended for single-patient, multi-use in a hospital or home care setting.	The Besmed Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.	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.	Similar

510(k) Substantial Equivalence Summary of Key Attributes

Product Features	Proposed Hudson RCI Triflo II Incentive Deep Breathing Exerciser	Predicate Besmed Incentive Spirometer (K133873)	Reference Hudson RCI Voldyne (K182847)	Assessment of Equivalence
Basic Components	 Housing 3 balls Tubing Mouthpiece Gross particulate filter	 Housing 3 balls Tubing Mouthpiece Gross particulate filter	 Housing 1 ball / piston Tubing Mouthpiece	Similar
Patient Population	Adult and pediatric (above 5 years) patients	Patients requiring inspiratory exercise	Adult and pediatric (above 5 years) patients	Similar
Environment	Hospital or home care setting.	Hospital or home care setting.	Hospital or home care setting.	Same
Principle of Operation	Non-powered; patient places mouth on mouthpiece and inhales.	Non-powered; patient places mouth on mouthpiece and inhales.	Non-powered; patient places mouth on mouthpiece and inhales.	Same
Sterilization Method	Non-sterile	Non-sterile	Non-sterile	Same
Patient Contacting Materials	Polystyrene, polypropylene, ethylene vinyl acetate, reticulated polyester polyurethane foam, dye	Thermoplastics	Thermoplastics	Similar
Usability	Single patient, Multi-use	Single Patient, Multi-use	Single Patient, Multi-use	Same

510(k) Substantial Equivalence Summary of Key Attributes

Product Features	Proposed Hudson RCI Triflo II Incentive Deep Breathing Exerciser	Predicate Besmed Incentive Spirometer (K133873)	Reference Hudson RCI Voldyne (K182847)	Assessment of Equivalence
Biocompatibility	• External communicating, Prolonged contact duration device that indirectly contacts tissue/bone/dentin. • Indirect gas pathway	• Surface, limited contact device that directly contacts intact skin • Indirect gas pathway	• External communicating tissue contact, limited duration	Similar
Standards Utilized	ISO 18562-1 ISO 18562-2 ISO 18562-3 ISO 10993-1 ISO 10339-5 ISO 10993-10 ISO 10993-11 ISO 10993-18	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11	Similar
Non-Clinical Testing	Packaging Simulated Distribution Environmental Conditioning (high and low humidity) Aging Flow testing/accuracy Useful life testing Cleaning process Drop testing	Aging Environmental (high and low humidity) Flow testing Drop testing	Age testing Mouthpiece and Tubing Engagement Test Tubing and Housing Engagement Test Collapsible Tubing Leakage Test Volume Accuracy Test Flow Chip and Piston Operation Slide Operation	Similar
Flow/Volume range	600, 900, and 1200 cc/sec	600, 900, and 1200 cc/sec	2500 and 4000 cc	Similar

510(k) Substantial Equivalence Summary of Key Attributes

Product Features	Proposed Hudson RCI Triflo II Incentive Deep Breathing Exerciser	Predicate Besmed Incentive Spirometer (K133873)	Reference Hudson RCI Voldyne (K182847)	Assessment of Equivalence
Accuracy of flow rate	Flow variation with nominal based on RMS calculation: 600 cc/s: 7.4% 900 cc/s: 9.3% 1200 cc/s: 4.6%	10% (RMS)	± 15%	Similar

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Hudson RCI Triflo II Incentive Deep Breathing Exerciser was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" issued September 4, 2020. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic toxicity
- Material Mediated Pyrogenicity
- Particulate Matter
- Volatile Organic Compounds

The following standards have been utilized:

- ISO 18562-1
- ISO 18562-2
- ISO 18562-3
- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 10993-11
- ISO 10993-18

Cleaning Validation
Cleaning validation was performed to verify the effectiveness of the manual cleaning effectiveness for the subject device using mild detergent. This study utilized a simulated test soil to evaluate the effectiveness of the cleaning procedure based on protein residual analysis, carbohydrate residual analysis and visual inspection.

Performance Bench Testing
The following bench testing was performed:

- Visual Inspection
- Flow Test/Accuracy
- Useful Life
- Flow Test After Useful Life
- Drop Testing
- Simulated Distribution
- Packaging

VIII. Conclusions

The subject device, the Hudson RCI Triflo II Incentive Deep Breathing Exerciser, is substantially equivalent to the predicate device, the Besmed TriBall.