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

May 27, 2015

Cohero Health LLC
c/o Mr. Paul Dryden
Consultant
335 Madison Avenue, 3rd Floor
New York, New York 10017

Re: K150137
Trade/Device Name: SpiroThor
Regulation Number: 21 CFR 868.1840
Regulation Name: Spirometer, diagnostic
Regulatory Class: II
Product Code: BZG
Dated: April 21, 2015
Received: April 22, 2015

Dear Mr. Dryden:

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.

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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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K150137

Device Name

SpiroThor

Indications for Use *(Describe)*

SpiroThor spirometer is a freestanding laboratory instrument for performing basic lung function tests in adults and children over the age of four years.

It is intended to be used by physicians or professional medical personnel for testing in physicians' offices, industrial medical, and hospital settings.

Type of Use *(Select one or both, as applicable)*

XX 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)*

510(k) Summary

Date Prepared: 26-May-2015

Cohero Health LLC
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Official Contact: Melissa Manice, Ph.D., CEO

Proprietary or Trade Name: SpiroThor

Common/Usual Name: Spirometer

Classification Name: 21CFR 868.1840
73 BZG – Spirometer, Diagnostic
Class II

Predicate Devices: K092813 – AstraSonic Spirometer
K051712 – Air Safety Model 2800 PFT Filter

Device Description:
The Cohero Health SpiroThor Spirometer is a hand-held portable diagnostic spirometer for the measurement of patient breath flow and volume. The proposed device consists of a compact main unit and an ultrasonic flowmeter sensor used with a pulmonary function filter. The device uses an ultrasonic sensor that measures flow. Algorithms are used to determine values based on this flow measurement. Tabular and graphical data are displayed on the spirometer LCD display.

We note that the proposed SpiroThor is identical to the AstraSonic Spirometer cleared under K092813 with these differences, name change and that another cleared bacterial filter may be used with the device.

Indications for Use:
SpiroThor spirometer is a freestanding laboratory instrument for performing basic lung function tests in adults and children over the age of four years.

It is intended to be used by physicians or professional medical personnel for testing in Physicians' offices, industrial medical, and hospital settings.

Substantial Equivalence Discussion:
The proposed device is substantially equivalent to the predicate device, manufactured by Thor Medical for SDI Diagnostics and cleared under the SDI name K092813 as the AstraSonic spirometer except as noted above, i.e. name change and another bacterial filter may be used.

Tables 1 and **2** compare the key features of the proposed SpiroThor with the identified predicate and demonstrate that the proposed device is substantially equivalent.

Table 1 – Comparison to Predicate

Specification	K092813 – SDI AstraSonic Diagnostic Spirometer	Proposed Device SpiroThor
Indications for Use	The SDI AstraSonic Spirometer is a freestanding laboratory instrument for performing basic lung function tests.	The SpiroThor Spirometer is a freestanding laboratory instrument for performing basic lung function tests.
Environment of Use	Physicians' offices, industrial medical and hospital settings	Physicians' offices, industrial medical and hospital settings
Patient Population	Adults and children over the age of four years	Adults and children over the age of four years
Temperature Sensor	Semiconductor (-25 ºC - +85 ºC)	Semiconductor (-25 ºC - +85 ºC)
Display	Graphic Quarter VGA (320x240 pixels), 262K colors	Graphic Quarter VGA (320x240 pixels), 262K colors
Keyboard	20-key keyboard	20-key keyboard
Connection Type	USB, BlueTooth	USB, BlueTooth
Flow Tube Dimensions	Ø30 mm x 150 mm	Ø30 mm x 150 mm
Power Supply	Internal 3.7 V Li-Ion battery (Rechargeable via 5V 500mA mini USB charger)	Internal 3.7 V Li-Ion battery (Rechargeable via 5V 500mA mini USB charger)
Dimensions	85x120x35 mm (Flow tube: 26 mm(ID)x150 mm)	85x120x35 mm (Flow tube: 26 mm(ID)x150 mm)
Weight	300g	300g
Flow/Volume	Bidirectional, ultrasound	Bidirectional, ultrasound
Measurement System	Ultrasonic technology (referred to as "WaveFront™ technology"	Ultrasonic technology (referred to as "WaveFront™ technology"
Volume Range	± 20 L (BTPS)	± 20 L (BTPS)
Flow Range	± 18 L/s (BTPS)	± 18 L/s (BTPS)
Volume Accuracy	± 3% or 50 mL	± 3% or 50 mL
Flow Accuracy	± 3% or 20 mL/s	± 3% or 20 mL/s
Dynamic Resistance at 14 L/s	< 1.1 $cmH_2O/L/s$	< 1.1 $cmH_2O/L/s$
Disposable in-line filter	AstraGuard – K062913	Air Safety – K051712
Electrical Protection	Internal battery power	Internal battery power
Printer	External printer via RS232 or BlueTooth	External printer via RS232 or BlueTooth

Table 2 – Comparison to Predicate

	Predicate K092813	**SpiroThor**
FVC (Forced Vital Capacity)	Yes	Yes
FEV.5 (Volume Expired in the first half second of test)	No	No
FEV1 (Volume Expired in the first second of test)	Yes	Yes
FEV3 (Volume Expired in the first three second of test)	Yes	Yes
FEV6 (Volume Expired in the first six second of test)	Yes	Yes
FEV1/FEV6 – Ratio	No	No
FEV.5/FVC – Ratio	No	No
FEV1/FVC – Ratio	Yes	Yes
FEV1/VC – Ratio	No	No
PEF (Peak Expiratory Flow)	Yes	Yes
FEF25 (Maximum flow at 25% of FVC)	Yes	Yes
FEF50 (Maximum flow at 50% of FVC)	Yes	Yes
FEF75 (Maximum flow at 75% of FVC)	Yes	Yes
FEF25-75 (Average flow between 25% and 75% of FVC)	Yes	Yes
FEF75-85 (Average flow between 75% and 85% of FVC)	No	No
FET25-75 (Time between 25% and 75% of FVC)	No	No
FET100 (Forced Expiratory Time)	Yes	Yes
FIVC (Forced Inspiratory Vital Capacity)	Yes	Yes
*FVC (Best FVC)	No	No
IVC (Inspiratory Slow Vital Capacity)	Yes	Yes
MVV (Maximum Voluntary Ventilation)	Yes	Yes
PIF (Peak Inspiratory Flow)	Yes	Yes
Te (Expiratory Time)	No	No
Ti (Inspiratory Time)	No	No
Ti/Tt (Ratio of Inspiratory Time to Total Time)	No	No
TV (Tidal Volume)	Yes	Yes
TV/Ti Ratio	No	No
VE (Minute Ventilation at Rest)	No	No
Vext (Extrapolated Volume)	Yes	Yes
VC (Slow Vital Capacity)	Yes	Yes

Differences:
The SpiroThor and predicate, K092813 – SDI AstraSonic Diagnostic Spirometer, are identical devices with minor differences. Namely, both products are produced by Thormed (“THOR”) and the only differences are the name of the device and that another bacterial filter may be used with the proposed device. THOR produced the SDI AstraSonic that was cleared in 2009, under the SDI AstraSonic name K092813.

There are no changes in technology, materials, design, performance, or any other difference that would render the device not substantially equivalent except as noted above.

In summary, one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K092813 – SDI AstraSonic Diagnostic Spirometer.
Discussion – Each device is indicated for use as a freestanding laboratory instrument for performing basic lung function tests in adults and children over the age of four years.

Technology and construction –
The design, components, shape, size, etc. are identical to the predicate, K092813 – SDI AstraSonic Diagnostic Spirometer.
Discussion – The technology and construction are identical to the predicate, K092813 – SDI AstraSonic Diagnostic Spirometer. It is noted that the proposed SpiroThor uses a different bacterial filter than the predicate, but comparative testing demonstrated that there is no differences in the performance of the SpiroThor with either filter.

Environment of Use –
The environments of use are identical to the predicate, K092813 – SDI AstraSonic Diagnostic Spirometer.
Discussion – physicians' offices, industrial medical and hospital settings.

Patient Population –
The patient population of adults and children over 4 years old.
Discussion – The patient populations are equivalent to the predicate, K092813 – SDI AstraSonic Diagnostic Spirometer.

Non-Clinical Testing Summary –
For K092813, THOR performed a number of bench tests.

These included:

- American Thoracic Society (ATS) 24 standard waveforms
- ISO 26782:2009
- Accuracy of waveform generator
- Flow resistance test
- EN 60601-1:2006/AC:2010
- EN 60601-1-2:2007/AC:2010
- EN 60601-1-6:2010
- Performance to specifications with each bacterial filter

The testing demonstrated that the SpiroThor performed as intended and met its performance specifications and was found to be substantially equivalent to the predicate K092813 – SDI AstraSonic Diagnostic Spirometer.

Materials:
The materials for each component, patient contact and predicate for the material per G95-1 and ISO 10993-1:2009 would be considered as both:

- External Communicating (Indirect gas pathway),
- Tissue contacting
- Duration of Use – limited (< 24 hours)

And

- Surface Contact
- Mucosal contacting
- Duration of Use – limited (< 24 hours)

The following tests would be required if a material certification cannot be provided.

- Cytotoxicity
- Sensitization
- Intracutaneous / Irritation

The materials are identical to the predicates and we have provided a material certification.

Clinical Testing –
No clinical testing was required or performed.

Discussion of Differences -
There are no significant differences between the proposed device and the predicate except that the proposed device may utilize the Air Safety PFT filter and a name change, but we have demonstrated that there are no functional performance differences between the AstraGuard and Air Safety filters.

Substantial Equivalence Conclusion –
All testing demonstrated that the proposed device is substantially equivalent to the predicate device.