DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 21, 2016

Shape Medical Systems, Inc.
% Mr. Bernard Horwath
Regulatory Consultant
Horwath Resource Group
4486 Timberline Ct.
St. Paul, Minnesota 55127

Re: K150888
Trade/Device Name: Shape-HF™ Cardiopulmonary Testing System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: BTY
Dated: December 18, 2015
Received: December 22, 2015

Dear Mr. Bernard Horwath:

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

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K150888

Device Name: Shape-HF™ Cardiopulmonary Testing System

Indications for Use:

The Shape-HF™ Cardiopulmonary Testing System is a pulmonary function stationary testing system intended to be used to monitor cardiopulmonary functions during stress testing, rehabilitation, sports medicine, and other related procedures for which cardiopulmonary gas exchange measurements are medically indicated. The System provides predictive pulmonary function values that are calculated based on the data obtained during testing. The System can be used on adults and children older than 14 years old in a laboratory or clinical facility setting.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Office of Device Evaluation (ODE)

510(k) Summary

Shape-HF™ Cardiopulmonary Testing System

Date Prepared: April 27, 2015 (Modified Jan 19, 2016)

Submitter: Shape Medical Systems, Inc
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Marketed Device: Shape-HF™ Cardiopulmonary Testing System

510(k) Clearance: K090722

Proprietary Name
Modified Device: Shape-HF™ Cardiopulmonary Testing System

Common/Usual Name: Cardiopulmonary Exercise Testing System

Classification Name: Predictive Pulmonary Function Value Calculator
21 CFR 868.1890, Class II, Product Code BTY

Establishment Registration Number: 3008072932

Description:
The Shape-HF™ Cardiopulmonary Testing System is a stationary device that monitors parameters during laboratory or clinical conditions. The Shape-HF™ Cardiopulmonary Testing System evaluates multiple variables of cardiorespiratory function. The System is intended to be used as a tool to aid in:

1. Cardiopulmonary health assessment;
2. Assessing heart and lung disease and defining probable sources of heart and/or lung limitations;
3. Assessing patient risk in heart and/or lung disease;
4. Assessing and monitoring physiological response to therapy, including pharmaceutical and/or medical device intervention; and
5. Assessing fitness levels and exercise tolerance.

Indications for Use:
The Shape-HF™ Cardiopulmonary Testing System is a pulmonary function stationary testing system intended to be used to monitor cardiopulmonary functions during stress testing, rehabilitation, sports medicine, and other related procedures for which cardiopulmonary gas exchange measurements are medically indicated. The System provides predictive pulmonary function values that are calculated based on the data obtained during testing. The System can be used on adults and children older than 14 years old in a laboratory or clinical facility setting.

Substantial Equivalence:
The Shape-HF™ Cardiopulmonary Testing System has the identical indications for use as the currently marketed device and is substantially equivalent to the following predicate devices:

- Shape-HF™ Cardiopulmonary Testing System, K090722
- Jaeger OxyconAlpha, K980094

Reference Table 1 for a summary of Substantial Equivalence Comparison.

Technological Characteristics:
The modified Shape-HF™ Cardiopulmonary Testing System has the same principle of operation and technology characteristics as the predicate Shape-HF™ Cardiopulmonary Testing System. The primary change is the Oxygen Sensor which is now a non-depleting Paramagnetic Cell, supplied by Servomex, rather than the previous Electro-chemical Cell. Both are considered standard oxygen sensing technologies. The Jaeger predicate device also utilizes the Paramagnetic Cell Oxygen Sensor. To accommodate the Paramagnetic Cell Oxygen Sensor the Shape-HF™ system housing was customized with slightly larger dimensions. The Shape-HF Software was also modified to accommodate the new O_2 Sensor and update the workload test protocols and user interface. In addition, the operating software in the lap top computer has been updated to Windows 7 from Windows XP. An on/off power switch has been added to the modified device for user convenience. The ECG device is optional intended to record the patient's electro-cardiogram. It is independent of the Shape-HF operation. Previously the ECG was user provided if desired; in the modified Shape-HF, a standard ECG device (Corscience K082077) is provided as a convenience to the user. All other technological aspects and performance specifications remain the same.

Biocompatibility:
No change to the patient contacting materials.

Safety Testing:
The modified Shape-HF™ Cardiopulmonary Testing System has been tested and conforms to the following standards:

- IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (version IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012)
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests (version IEC 60601-1-2:2007, Non-Life Supporting Equipment)

Performance Bench Testing:
The modified Shape-HF™ Cardiopulmonary Testing System was tested to verify its equivalence to the current predicate Shape-HF™ system. Testing included System Verification and Validation test, Software Validation, and a Comparison verification test utilizing the current and modified systems. All testing was successful and demonstrated that functional performance requirements were met.

Conclusion:
Through the data and information presented, Shape Medical Systems, Inc. considers the modified Shape-HF™ Cardiopulmonary Testing System substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design and functional performance and present no new concerns about safety and effectiveness.

Table 1 Substantial Equivalence Comparison

Device(s)	Modified Shape-HF™ Cardiopulmonary Testing System	Shape-HF™ Cardiopulmonary Testing System	Oxycon Alpha
Manufacturer	Shape Medical	Shape Medical	Jaeger
510(k) Number Decision Date		K090722 March 31, 2009	K980094 July 28, 1998
Classification Name	Predictive Pulmonary Function Value Calculator; 21 CFR 868.1890, Class II, Product Code BTY	Predictive Pulmonary Function Value Calculator; 21 CFR 868.1890, Class II, Product Code BTY	Predictive Pulmonary Function Value Calculator; 21 CFR 868.1890, Class II, Product Code BTY
Indications for Use	The Shape-HF™ Cardiopulmonary Testing System is a pulmonary function stationary testing system intended to be used to monitor cardiopulmonary functions during stress testing, rehabilitation, sports medicine, and other related procedures for which cardiopulmonary gas exchange measurements are medically indicated. The System provides predictive pulmonary function values that are calculated based on the data obtained during testing. The System can be used on adults and children older than 14 years old in a laboratory or clinical facility setting.	The Shape-HF™ Cardiopulmonary Testing System is a pulmonary function stationary testing system intended to be used to monitor cardiopulmonary functions during stress testing, rehabilitation, sports medicine, and other related procedures for which cardiopulmonary gas exchange measurements are medically indicated. The System provides predictive pulmonary function values that are calculated based on the data obtained during testing. The System can be used on adults and children older than 14 years old in a laboratory or clinical facility setting.	The Jaeger Oxycon Alpha is a predictive pulmonary function value calculator. It is a software driven, active medical device for investigational exercise measurements. It measures the human response to increasing workloads with emphasis on the gas exchange parameters. Measurements include ventilation, oxygen uptake, carbon dioxide production, and derived parameters.
Principle of Operation	The Shape-HF™ System is a mobile instrument to be used for breath-by-breath measurement during cardiopulmonary metabolic gas exchange exercise testing (CPX).	The Shape-HF™ System is a mobile instrument to be used for breath-by-breath measurement during cardiopulmonary metabolic gas exchange exercise testing (CPX).	The OxyconAlpha System is a mobile instrument to be used for breath-by-breath measurement during cardiopulmonary metabolic gas exchange exercise testing (CPX).
Intended Population of Use	Adult or children over 14 years of age.	Adults or children over 14 years of age.	Patient population is 4 years of age and older.
Environment of Use	Laboratory or healthcare facility location.	Laboratory or healthcare facility location.	Laboratory or healthcare facility location.
Expired/inspired air Flow Measurement	Fixed orifice, differential pressure pneumotach	Fixed orifice, differential pressure pneumotach	Digital rotameter
Carbon Dioxide analyzer	Non-dispersive infrared	Non-dispersive infrared	Non-dispersive infrared
Oxygen Analyzer	Paramagnetic cell, non-depleting	Electrochemical fuel cell	Paramagnetic cell
ECG	Optional	Optional-User provided	Unknown
Heart Rate	Pulse Oximeter	Pulse Oximeter	Polar Heart Rate Monitor
Signal Processing	PC based DLL	PC based DLL	Unknown
Primary Measurements	Breath count, $PetCO_2$, VCO_2, VO_2, VT, Heart Rate, Respiratory Rate, Barometric Pressure, SPO_2, Dead Space, Peak Expiratory Flow, Volume Inspired, Resting Energy, Expiratory Time, Inspiratory Time, and measurements derived from these.	Breath count, $PetCO_2$, VCO_2, VO_2, VT, Heart Rate, Respiratory Rate, Barometric Pressure, SPO_2, Dead Space, Peak Expiratory Flow, Volume Inspired, Resting Energy, Expiratory Time, Inspiratory Time, and measurements derived from these.	Measurements include ventilation, oxygen uptake, carbon dioxide production, and derived parameters.
Software Op System	Windows 7	Windows XP	Unknown
Safety Testing	IEC 60601-1; IEC 60601-1-2	IEC 60601-1; IEC 60601-1-2	Unknown
Operating Voltage	Input: 90/240 VAC; 50 – 60 Hz Output: 5/12 VDC; 3 A	Input: 90/240 VAC; 50 – 60 Hz Output: 5/12 VDC; 3 A	Input: 90/240 VAC; 50 – 60 Hz Output: 5/12 VDC; 3 A