K090722

510(k) Summary of Safety and Effectiveness
(As required by 807.92(c))

MAR 31 2009

Submitter:

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Contact Information:

On behalf of Shape Medical Systems, Inc., the following consultant is assigned the responsibility of submission correspondence:

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Submission Date: September 15, 2008

Trade Name: Shape-HF™ Cardiopulmonary Testing System

Classification Name: Predictive Pulmonary Function Value Calculator (21 CFR Section 868.1890)

Predicate Device: Cortex Metalyzer 3B™

Device Description and Comparison:

The Shape-HF Cardiopulmonary Exercise Testing System is a stationary device that monitors parameters during laboratory or clinical conditions. The Shape-HF system is comparable to the Cortex Metalyzer 3B™ system (K993641).

The device is software driven and electrically operated.

Intended 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.

Differences and Similarities: The Shape-HF™ Cardiopulmonary Testing System is substantially equivalent to the predicate device.

Intended Use: The intended use of the Shape-HF System and the predicate device are equivalent.

Applications: Both devices are used in applications such as stress testing, rehabilitation, occupational medicine, sports medicine, physiological research, and therapeutic assessment.

Usage location: Both devices are designed for use in a laboratory or clinical facility setting.

Technology: The Shape-HF system and the predicate device have very similar technology in their components.

Similarities:

Carbon dioxide sensor – Non-dispersive infrared in both systems.
Oxygen sensor – Electrochemical fuel cell in both systems.
Predictive value calculations – Both systems measure the same variables and then calculate values for pulmonary function.
Intended population – Both systems are intended for use on adults or children over 14 years of age.

Differences:

Heart rate sensor – The Shape-HF System uses a pulse oximeter for sensing heart rate and the predicate device uses a Polar Belt. Both types are considered standard technology for heart rate sensing.
Volume transducer – The Shape-HF System uses a fixed orifice, differential pressure pneumotach while the predicate uses a digital rotameter. Both methods are considered standard technology for measuring expired/inspired air flow.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shape Medical Systems, Incorporated
C/o Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

MAR 31 2009

Re: K090722
Trade/Device Name: Shape-HF™ Cardiopulmonary Exercise Testing System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Valve Calculator
Regulatory Class: II
Product Code: BTY
Dated: March 18, 2009
Received: March 19, 2009

Dear Mr. Lehtonen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090722

Device Name: Shape-HF™ Cardiopulmonary Exercise 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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