K090646

510(k) Summary

(per 21 CFR 807.92(c))

1. Applicant

JUL 23 2009

CHEST M. I., Inc.
3-6-10 Hongo Bunkyo
Tokyo, Japan 113-0033

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Date Prepared: January 19, 2009

2. Device Name

Trade Name: CardioTech GT-105 Spirometer
Common/ Usual Name: Spirometer, Diagnostic
Classification Name: Diagnostic Spirometer
Regulation Number: 868.1840
Product Code: BZG
Classification: II
Panel: Anesthesiology

3. Predicate Devices

The CardioTech Spirometer is substantially equivalent to the following devices:

510(k) Number	Device	Applicant
K022103	PB700 Renaissance II Spirometry System	Puritan Bennett Inc.
K031102	Microlab Spirometer	Micro Direct, Inc.

4. Indications for Use

The CardioTech Spirometry System, Model GT-105, is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician's offices, laboratories, and occupational health environments.

5. Description of the Device

The CardioTech GT-105 Spirometry System measures a wide range of physiological parameters such as SVC, FVC, MVV, and MV and consists of a spirometer and a flow sensor.

The flow sensor head, which includes a flow air resistance element, is mounted on the flow sensor body. Via a disposable mouthpiece and filter, the patient breathes as instructed through the flow sensor head. The pressure transducer in the spirometer then measures the differential pressure in the flow sensor head which is digitized into 12 bit data by an A/D converter.

The data can be transferred via RS-232C/USB interfaces to a PC in which Spirobank software is installed. Since the software includes a number of screens and 'buttons' that help to logically perform the function, the medical practitioner (e.g., technician) can print (reports), save and recall the data/results.

6. Summary of the Technical Characteristics

- Electrical Testing

  The CardioTech Spirometry System was tested in accordance with the medical electrical equipment requirements defined by IEC 60601-1-2:2001 + A1:2005 and IEC 60601-1:1998 + A1:1991 + A2:1995 for electromagnetic compatibility and electrical safety, respectively.

- Performance Testing

  The CardioTech Spirometry System was tested in accordance with the industry standard developed by the American Thoracic Society.[1]

7. Safety and Effectiveness

The CardioTech GT-105 Spirometry System is a safe and effective device and is substantially equivalent to the predicate devices listed in this 510(k) submission; that is, the CardioTech GT-105 Spirometry System has the same indications for use and is similar in both design and function. Any differences in technological characteristics between the CardioTech GT-105 Spirometry System and the predicate devices do not raise issues of safety and effectiveness.

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[1] American Thoracic Society Standardization of Spirometry 1994 Update. Am J Respir Crit Care Med 1995, 152: 1107-1136.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chest M.I. Incorporated
C/O Ms. Jean Asquith
Senior Regulatory Consultant
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

JUL 23 2009

Re: K090646
Trade/Device Name: CardioTech Spirometry System, Model GT-105
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: July 6, 2009
Received: July 8, 2009

Dear Ms. Asquith:

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.

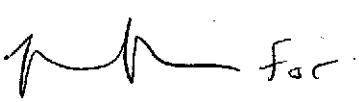
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
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): _____

Device Name: CardioTech Spirometry System, Model GT-105

Indications for Use:

The CardioTech Spirometry System, Model GT-105, is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician's offices, laboratories, and occupational health environments.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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