K092813

JUL 13 2010

510(k) Summary

March 10, 2010

[As Required by 21 CFR 807.92]

Owner / Submitter of 510(k)	SDI Diagnostics, Inc. Michael J. Boyle - President 10 Hampden Drive Easton, MA 02375 e-mail: mjboyle@sdidiagnostics.com
Establishment Registration No.:	1221256
Contact:	Cosimo Cariolo e-mail: ccariolo@sdidiagnostics.com Tel: (508) 238-7033, fax (508) 230-8497
Trade Name:	SDI AstraSonic Diagnostic Spirometer
Common Name:	Spirometer
Classification Name:	Spirometer, Diagnostic
Regulation Number	868.1840
Classification Panel:	Anesthesiology
Regulatory Class:	II
Product Code:	BZG
Predicate Device	510(k) #K993921 ndd Medical Technologies EasyOne Spirometer
Device Description:	The AstraSonic Diagnostic Spirometer is a hand-held portable diagnostic spirometer for the measurement of patient breath flow and volume. The device uses an ultrasonic transducer 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.
Intended Use:	The SDI AstraSonic 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.

Technological Comparison:	The AstraSonic spirometer has the same technological characteristics as the predicate device, except that the predicate device has a disposable transducer mouthpiece that is an integral part of the circuit. The Astrasonic spirometer utilizes a cleanable transducer and a disposable filter mouthpiece that is inserted into the transducer. Testing was conducted to demonstrate that the measurement of flow by the device was equivalent in accuracy to the predicate device.
Summary of Testing:	A direct comparison of the Astrasonic spirometer and the predicate device was made using the 26 waveforms described by the American Thoracic Society to determine substantial equivalence.
Conclusion:	Based on the above, we have concluded that the SDI AstraSonic Spirometer is substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 15 2010

Mr. Cosimo Cariolo
Director of Marketing
SDI Diagnostics, Incorporated
10 Hampden Drive
Easton, Massachusetts 02375

Re: K092813
Trade/Device Name: SDI AstraSonic Diagnostic Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: July 14, 2010
Received: July 15, 2010

Dear Mr. Cariolo:

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 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/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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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:

Device Name: AstraSonic™ Spirometer

Indications for Use:

The SDI AstraSonic 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K092813

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