K061571

sdi

DIAGNOSTICS

JAN 31 2007

510(k) Summary

[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 Tel: (508)238-7033, fax (508)230-8497 e-mail: mjboyle@sdidiagnostics.com
Establishment Registration No.:	1221256
Contact:	Cosimo Cariolo e-mail: ccariolo@sdidiagnostics.com
Trade Name:	SDI ASTRA 300 Diagnostic Spirometer With or Without Pulse Oximetry Function
Common Name:	Spirometer
Classification Name:	Spirometer, Diagnostic
Regulation Number	868.1840
Classification Panel:	Anesthesiology
Regulatory Class:	II
Product Code:	BZG, DQA
Predicate Devices	510(k) #K013812 SDI Spirolab II Spirometer 510(k) #K031863 Motion Media Technology CareStation 126S
Device Description:	The ASTRA 300 Diagnostic Spirometer is a hand-held portable diagnostic spirometer for the measurement of patient breath flow and volume.The device uses a turbine transducer that measures flow via infrared interruption. Algorithms are used to determine values based on this flow measurement. Tabular and graphical data are displayed on the spirometer LCD display.

Device Description (cont'd): With the optional Pulse Oximeter module, the specific patient parameters oxygen saturation in the blood (SpO2) and pulse rate, both relating to the patient's pulmonary condition, may be measured and displayed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 3 1 2007

Re: K061571
Trade/Device Name: Astra 300
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: January 29, 2007
Received: January 30, 2007

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.

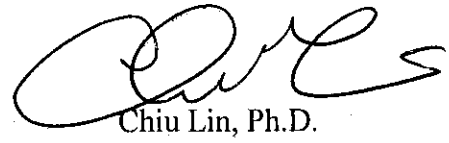
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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: K061571

Device Name: Astra 300

Indications For Use: The SDI Astra 300 Spirometer is a freestanding laboratory instrument for performing basic lung function tests and oximetry in people of all ages. It is intended to be used by physicians or professional medical personnel for testing in any setting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061571