K062913

510(k) Summary

JAN 26 2007

[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 AstraGuard Pulmonary Function filter
Common Name:	Disposable PFT Filter
Classification Name:	Filter, Bacterial
Regulation Number	21 CFR 868.5260
Classification Panel:	Anesthesiology
Regulatory Class:	II
Product Code:	CAH
Predicate Devices	510(k) #K934509 SDI Pulmoguard Filter 510(k) #K043148 Alliance Tech Medical All Flow Filter 510(k) # K934475 Koko Disposable PFT Filter II
Device Description:	The SDI AstraGuard Pulmonary Function Filter is an electrostatic polypropylene medium enclosed in a molded polystyrene shell. The highly efficient medium is ultrasonically welded to the shell body.
Intended Use:	The AstraGuard Pulmonary Function Filter is intended for use in reducing possible bacterial and/or viral cross contamination of spirometers and pulmonary testing instruments, associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. The device is indicated for diagnostic applications.

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 26 2007

Re: K062913
Trade/Device Name: AstraGuard Pulmonary Function Filter
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: January 10, 2007
Received: January 16, 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.

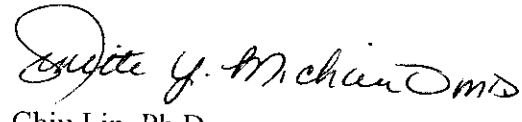
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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 STATEMENT

510(k) Number (if known) K062913

Device Name: AstraGuard Pulmonary Function Filter

Indications for Use:

The AstraGuard Pulmonary Function Filter is intended to for use in reducing possible bacterial and/or viral cross contamination of spirometers and pulmonary testing instruments, associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. The device is indicated for diagnostic applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K062913

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)