MAY 12 2000 K992823

SCHILLER
SWITZERLAND

FDA 510K SP-2

510 K Summary

according to 21 CFR 807.92

A1 Address

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Contact Name: Mr. Markus Buetler
Tel: 001 41 41 766 4252
(Date: 9th December 1999)
Revision Date: 4th May 2000

A2 Device Name

1. Trade Name: SPIROVIT SP-2 / PneumoCheck ® II
2. Common Name: Spirometer, Pulmonary Function Test Device

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:
SP-250 (K984031).

A4 Intended Use

The Spirovit SP-2 / PneumoCheck ® II can be used to measure the following spirometric parameters within the Healthcare Facility:

Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), $FEV_{1.0}$ / FVC, $FEF_{0.2\text{-}1.2}$, $FEF_{25\text{-}75\%}$, $FEF_{75\text{-}85\%}$, PEF, $FEF_{25\%}$, $FEF_{50\%}$, $FEF_{75\%}$, FIVC, $FIV_{1.0}$, $FIV_{1.0}$ / FIVC, PIF, $FIF_{50\%}$, SVC, ERV, IRV, TV, MVV, MV, RR, TV, in patients 6 years of age or older.

A5 Table of Comparison

Predicate device: SPIROVIT SP-250 (K984031)

		SP-250 (K984031)		SPIROVIT SP-2 PneumoCheck ® II
Dimensions:				
Flow Sensor		7.5 cm		[1] 85x190x27 mm
Handle		10 cm		n.a.
Mouthpiece		disposable		same
Weight:		180 g		[2] 275 g
Environmental Conditions:				
Operating temperature		+10° - 40° C		same
Storage temperature		-10° - +50° C		same
Relative humidity		25% - 95% (non condensing		same
Electrostatic Discharge / Electromagnetic Compatibility:				
ESD		Fully functional below 4 kV (Open Air)		same
		No damage below 8 kV (Open Air)		same
Radiated Emissions		Less than 30 dB Microvolts		same
Radiated Immunity		3 Volts per meter		same
Data Communication		RS-232 interface		[3] IrDA

Discussion of Differences:
None of the above differences (1, 2 or 3) can be considered as safety relevant differences.
We consider the submitted device to be as safe and effective as the Predicate (SP-250) device.

B1 Non-Clinical Tests

1. Electrical Safety and Reliability
   The SPIROVIT SP-2 / PneumoCheck ® II device has been tested to be in accordance with the following standards:
   - ATS Spirometry Statement Medical Section of the American Lung Association November 11th 1994
   - IEC 601-1-1 (Safety)
   - IEC 601-1-2 (EMC)
   - IEC 601-1-4 (Software Quality)

   All tests are passed.

4) Data related to software quality
   SCHILLER has reviewed its software development process following the guideline
   " reviewer guidance for computer controlled medical devices undergoing 510 (k) review". Device software requirements, software structure chart, software development, software revision/ modification, software identification, software verification, validation and testing are described in the data attached.

B2 Clinical Tests

n.a.

B3 Conclusions from Tests

The fulfilling of the above standards ensures the safety and effectiveness of the submitted device. We consider the submitted device to be as safe and effective as the Predicate (SP-250) Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Mr. Markus Buetler
Schiller AG
Altgasse 68, Postfach
CH-6341 BAAR
SWITZERLAND

Re: K992823
Spirovit SP-2/PnuemoCheck II
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: March 7, 2000
Received: March 9, 2000

Dear Mr. Buetler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 992823

Device Name: SPIROVIT SP-2

Indications For Use:

The Spirovit SP-2 / PneumoCheck ® II can be used to measure the following spirometric parameters within the Healthcare Facility:

Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), $FEV_{1.0}$ / FVC, $FEF_{0.2\text{-}1.2}$, $FEF_{25\text{-}75\%}$, $FEF_{75\text{-}85\%}$, PEF, $FEF_{25\%}$, $FEF_{50\%}$, $FEF_{75\%}$, FIVC, $FIV_{1.0}$, $FIV_{1.0}$ / FIVC, PIF, $FIF_{50\%}$, SVC, ERV, IRV, TV, MVV, MV, RR, TV, in patients 6 years of age or older.

(PLEASE DO NO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992823

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)