SCHILLER AG
K050885

510 K Summary

MAY - 4 2005

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: 15.March 2005

A2 Device Name

1. Trade Name: CARDIOVIT AT-10Plus
2. Common Name: Electrocardiographie Device

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:
AT-102 (K031557)

A4 Intended Use

The AT-10Plus is a 12-channel, ECG device used for the recording, analysis and evaluation of ECG recordings. Recordings made with the AT-10Plus can be used as a diagnostic aid for the heart function and heart conditions. The AT-10Plus is designed for indoor use.
The device provide an optional interface to the SP-250 pulmonary function data.

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A5 Table of Comparison

Predicate device: CARDIOVIT AT-102 (K031557)

	AT-102 K031557	CARDIOVIT AT-10Plus
Dimensions:	380x328x100mm	348x288x87mm [1)]
Weight:	5.0 kg	4.2 Kg
Environmental Conditions:		
Operating temperature	+10° - 40° C	same
Storage temperature	-10° - +50° C	same
Relative humidity	25% - 95% (non condensing	same
Leads:	Standard / Cabrera	same
Battery capacity:	2 hrs of normal use	same
Frequency range of digital recorder:	0 to 150Hz	same
Control panel	Alphanumerics, LCD Display	Alphanumerics, LCD Display 800x600dots [2)]
Myogram Filter	25Hz or 35Hz programmable	same
Paper speed	5/10/25/50mm/s direct	5/10/12.5/25/50 [3)]
Printing process	High resolution thermal printhead 8dots per mm 200dots per inch(amplitude axes) 40dots per mm / 1000 dots per inch time axes, 25mm/s	same
Chart paper	Thermoreactive, Z-folded, 210mm	same
Recording tracks	6 channels, positioned at optimal with on 80 mm / 3.2 inch automatic baseline adjustement	same
Automatic lead programs	6 channel representation of 12 simultaneously acquired standard leads	same
Spirometry	SP-250 (K984031)	same

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 (AT-102) device.

B1 Non-Clinical Tests

1. Electrical Safety and Reliability
   The CARDIOVIT AT-AT-10Plus device has been tested to be in accordance with the following standards:

   - **EN60601-1** Medical Electrical Equipment: essential requirements for safety (Document no.: 052-077403-000)
   - **IEC 601-2-25** Medical Electrical Equipment: requirements for the safety of electrocardiographs (Document no.: 052-077403-000)

   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 (AT-102 K031557) Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

SCHILLER AG
c/o Mr. Markus Buetler
Quality Assurance and Regulatory Affairs Manager
Altgasse 68 CH-6341 Baar
SWITZERLAND

Re: K050686
Trade Name: CARDIOVIT AT-10Plus ECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 15, 2005
Received: March 17, 2005

Dear Mr. Buetler:

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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050686

Device Name: Cardiovit AT-10Plus

Indications for Use:

The AT-10Plus is a 12-channel, ECG Device used for the recording, analysis and evaluation of ECG recordings. Recordings made with the AT-10Plus can be used as a diagnostic aid for heart function and heart conditions. The AT-10Plus is designed for indoor use.
The device provide an optional interface to the SP-250 for pulmonary function data.

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15/03/05

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050686