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510 K Summary

APR - 8 2002

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: 02.th April 2002

A2 Device Name

1. Trade Name: Argus PB-1000 System
2. Common Name: Monitoring System

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:

Cardiovit CS – 200 K 970879

A4 Intended Use

The Monitoring System ARGUS PB-1000 is for the monitoring of vital parameters such as:

ECG: Heartrate, Asystolic Time, Respiration Rate
Invasive Blood Pressure: systolic, distolic and mean pressure
Temperature: temperature and ΔT
Non Invasive Blood Pressure: systolic, distolic and mean pressure
CO_2, etCO_2 and CO_2ins
SpO_2: SpO_2 and pulse rate

on humans and for the evaluation of Resting ECG, Arrhythmias, ST-Segments and Cardiac Output. There is alarm handling for all parameters except ST-Segments.
The system comprises the Parameter Box PB-1000 and the Visualisation Unit ARGUS PRO. The two units are connected via a serial interface.
All vital parameters and evaluations are registered and calculated in the PB-1000. This data is then transmitted to the visualisation unit ARGUS PRO or another generally used PC via the serial interface. All data can be shown and monitored on the ARGUS PRO.
The PB-1000 operated using an internal battery and an external power input (RS 232/12V), which is, like the data transmission, completely separate from the visualisation unit. The ARGUS PRO is powered via the normal mains connection 230V/110V.

The system is inteded for use in the Intensive Care Unit, in the Recovery Room, in the Operation Room and during hospital internal transport.

A5 Table of Comparison

		CS-200 (K970879)		PB-1000
Dimensions:		600x620x1530mm		210x115x45mm [1)]
Weight:		71 kg		980 g [2)]
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:		EN 60601-1-2		same
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		Less than 3 Volts per meter		same

Discussion of Differences:
None of the above differences (1 or 2) can be considered as safety relevant differences.
We consider the submitted device to be as safe and effective as the Predicate Cardiovit CS-200 (K970879) device.

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B1 Non-Clinical Tests

1. Electrical Safety and Reliability
   The device has been tested to be in accordance with the following standards:
   EN 60601-1:1990: *Safety of Medical Electrical Equipment part 1, General requirements.*
   EN 60601-1-1:1993 *Safety requirements for medical electrical systems.*
   EN 60601-1-2: *Electromagnetic Compatibility Test, Electrostatic Discharge, Radio Frequency Electromagnetic Field, Fast Transients.*
   EN 60601-1-4:1996 *Collateral Standard: Programmable electrical medical systems.*
   EN60601-2-25:1996 *Particular requirements for the safety of electrocardiographs.*
   EN 60601-2-27:1996 *Particular Requirements for the safety of electrocardiographic monitoring equipment.*
   EN 60601-2-30:1995 *Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment.*

   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 Cardiovit CS-200 (K970879) Device.

Date: 02.04.2002

Markus Buetler
Quality Assurance Manager
SCHILLER AG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2002

Mr. Markus Buetler
Quality Assurance Manager
SCHILLER AG
Altgasse 68, Postfach
CH-6341 Baar
SWITZERLAND

Re: K012226
Trade Name: Argus PB-1000 System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detection or Alarms
Regulatory Class: Class III (three)
Product Code: MHX
Dated: March 8, 2002
Received: March 11, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). 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,

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

Enclosure

K012226

SCHILLER SWITZERLAND	Indications for Use ARGUS PB - 1000	Nr. : Issue : 07.03.02 Page : 1 /1

ARGUS PB-1000 System

Indications for Use

The Monitoring System ARGUS PB-1000 is for the monitoring of vital parameters such as:

ECG: Heartrate, Asystolic Time, Respiration Rate

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Temperature: temperature and ΔT

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07.03.2002

Division of Cardiovascular & Respiratory Devices
510(k) Number K012226

Prescription Use X
(Per 21 CFR 801.109)