

AUG 25 1998

K973735

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SWITZERLAND

510 K Summary

according to 21 CFR 807.92

A1 Address

SCHILLER America, Inc.
3002 Dow Avenue, #138
Tustin, CA 92780

Contact Name: Mr. Markus Maritz
Tel: (619) 635 6023
Date: 26th September 1997

A2 Device Name

1. Trade Name: Microvit MT-100
2. Common Name: Solid State Holter Recorder
3. Classification Name: Medical Magnetic Tape Recorder (Class II)

Classification Class: 74 DSH

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:
Braemar DL 700 Holter Monitor (K946130)

A4 Description of Submitted Device

The ECG Holter device, MICROVIT MT-100, is a recording device used to record long term Electrocardiographs for 24 hours, on two channels.

A5 Intended Use

The ECG Holter device, MICROVIT MT-100, is a recording device used to record long term Electrocardiographs for the diagnostics of symptomatic and asymptomatic arrhythmias.

1. Patient Population:
human beings without restrictions of age, sex or race.

2. Difference to the Predicate Device:
mode of data transmission to the analysis station.

Predicate Device: PCMCIA Card

Submitted Device: Serial Optical Transmission.

The maximum deviation between the original ECG signal and the transmitted and restored ECG signal is less than 20 microvolts. This difference in transmission rises no concern regarding the safety and effectiveness of the device.

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A6 Table of Comparison

Predicate device: Braemar DL 700 Holter Monitor (K945130)

	<u>DL 700</u>	<u>MT - 100</u>	
<u>Dimensions</u>	6.0"x3.5"x0.95"	4.3" x 2.7" x 0.7"	
<u>Weight</u>	10 ounces incl. batteries	140g, 5 ounces incl. batteries	
<u>Battery:</u>	1.5V Alkaline AA	SAME	
<u>Channels</u>	2 or 3	2	
<u>Environmental Conditions</u>			
<i>Operating temperature</i>	0 to 70 degree Celsius	+10 to +40 C	1)
<i>Storage temperature</i>	-40 to +50 degree Celsius	-10 to +50 C	
<i>Relative humidity</i>	10% to 90% (non condensing)	25% to 95% (non condensing)	
<u>ECG Amplifier</u>			
<i>Input Impedance</i>	> 5 MOhm	> 10 MOhm	2)
<i>DC Offset</i>	± 300mVDC max.	SAME	
<i>Common Mode rejection</i>	60dB	> 80dB	3)
<i>Recording Bandwidth</i>	0.05 Hz to 50 Hz	0.05Hz to 40 Hz	4)
<u>Recording Time</u>	24 hours	SAME	
<u>Electro Static Discharge / Electro Magnetic Compatibility</u>			
<i>ESD</i>	Fully functional below 4 kV (Open Air)	SAME	
	No damage below 8kV (Open Air)	SAME	
<i>Radiated Emissions</i>	Less than 30 dB Microvolts	SAME	
<i>Radiated Immunity</i>	Less than 3 Volts per meter	SAME	

Discussion of differences

1. Environmental conditions claimed are in accordance with MIL-STD-81D.
No concern related to safety and effectiveness of the device.
2. Input Impedance claimed are in accordance with AAMI EC38-1994.
No concern related to safety and effectiveness of the device.
3. Common Mode Rejection claimed are in accordance with AAMI EC38-1994.
No concern related to safety and effectiveness of the device.
4. Recording Bandwidth claimed are in accordance with AAMI EC38-1994.
No concern related to safety and effectiveness of the device.

B1 Non-Clinical Tests**1. Electrical Safety and Reliability**

The Microvit MT-100 device has been tested to be in accordance with the following standards:

- ANSI / AAMI, EC 38-1994: *Ambulatory Electrocardiographs Type 1 Devices*
- IEC 601-1:1988: *Safety of Medical Electrical Equipment part 1, General requirements*
- IEC 801-1:1984, IEC 801-2:1991, IEC 801-3:1984, *Electromagnetic Compatibility Test, Electrostatic Discharge, Radio Frequency Electromagnetic Field.*

All tests are passed.

2. Environmental Testing

The following environmental tests have been conducted:

- mechanical tests (vibration, shock, fall, toppling) (IEC 601-1, MIL-STD-81D)
- climate tests (storage/operation temperatures) (MIL-STD-81D)

All tests are passed.

3. Electro Magnetic Compatibility (EMC)

The following electromagnetic magnetic compatibility tests have been conducted:

- EN 55011 class B Electromagnetic radiation
- IEC 801-1 Electromagnetic susceptibility
- IEC 801-2 Electrostatic Discharge
- IEC 801-3 Radio Frequency Electromagnetic Field

All tests are passed. The test reports are enclosed.

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 fulfillment 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 (Braemar) Device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1998

Mr. Markus Maritz
Schiller America, Inc.
3002 Dow Avenue, Suite 138
Tustin, CA 92780

Re: K973735
Microvit MT-100
Regulatory Class: II (two)
Product Code: 74 DSH
Dated: May 29, 1998
Received: June 2, 1998

Dear Mr. Maritz:

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 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.

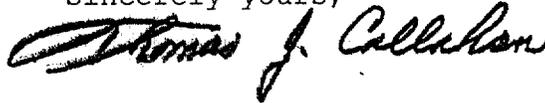
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Markus Maritz

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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 973735

Device Name: Holter MICROVIT MT-100

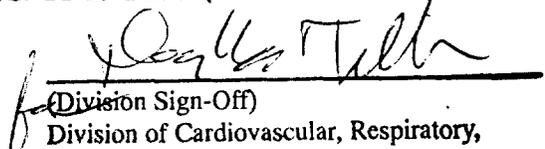
Indications For Use:

The ECG Holter device, MICROVIT MT-100, is a recording device used to record long term Electrocardiographs for the diagnostics of symptomatic and asymptomatic arrhythmias, i.e. bradycardia, tachycardia, diagnostic of arrhythmias in patients with coronary artery disease, in patients after reanimation, in patients with different diseases such as cardiomyopathy, high blood pressure, long QT syndrome.

A Holter ECG recording is also used for clarifying palpitations or syncopes and attacks of dizziness or for controlling medical therapies, or after operative treatments such as bypass operations or PTCA. The ST segment analysis of a Holter ECG is used for the detection of symptomatic or asymptomatic ischemias.

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K973735

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-90)