

K 973751

AUG 25 1998

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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 Martz
Tel: (619) 635 6023
Date: 22nd September 1997

A2 Device Name

1. Trade Name: Microvit MT-200
2. Common Names: Holter System, Holter Analyzer
3. Classification Name: Computer, Diagnostic, Programmable

Panel Code: DOK (CV) 74
Classification Class: Computer Diagnostic Programmable Class 2

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:
Brentwood Rhythmscan Precision CS-6000 (K914577)

A4 Description of Submitted Device

The ECG Holter evaluation software, MT-200, is an analysis software used for the analysis and evaluation of Holter ECG recordings. The Holter recordings are used for the diagnostics of symptomatic and asymptomatic arrhythmias, i.e. bradycardia, tachycardia, diagnostic of arrhythmias in patients with coronary artery disease, in 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.

The software runs on Windows™ 95.

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A5 Intended Use

The ECG Holter Analyzer MT-200, is a ECG analyzing software for the diagnostics of symptomatic and asymptomatic arrhythmias and of Ischemic episodes.

1. Patient Population: human beings without restrictions of age, sex or race.
2. Difference to the Predicate Device: no differences.

A6 Table of Comparison

Predicate device: Brentwood Rhythmscan Precision CS-6000 (K914577)

	<u>Precision CS-6000</u>	<u>MT-200</u>
<u>Recording Medium</u>	Tape cassette and Solid state recorder DL 700	Solid state recorder MT-200
<u>Channels</u>	2 or 3	2
<u>System requirements</u>		
<u>CPU</u>	IBM compatible PC 386, 33 MHz 8 Mbytes RAM 80 Mbytes Hard-drive Windows™ 3.11 or 95	IBM compatible PC 486, 66 MHz 16 Mbytes RAM 100 Mbytes Hard-drive Windows™ 95
<u>Monitor</u>	VGA Color Monitor	SAME
<u>Printer</u>	HP Laser Jet Series	SAME

B1 Non-Clinical Tests

Data related to software quality

SCHILLER has reviewed the MT-200 Analyzer Software development process following the guideline "reviewer guidance for computer controlled medical devices undergoing 510 (k) review".

All tests are passed.

B2 Clinical Tests

To evaluate the performance of arrhythmia detection of the MT-200 program, the AHA and MIT data bases were used and the annotations in the databases compared with the automatic analysis carried out by the MT-200 program.

Method

A normal analysis of the AHA and MIT records was carried out by the MT-200. The classifications given by the MT-200 were then compared with the annotated classifications of the data bases.

The results of the comparison were given in tabular form.

The procedure and limits described in ANSI/AAMI EC 38-1994 were used.

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For the evaluation of the ST-T analysis the ESC ST.T. database was used. The ST-segment deviations measured by the MT-200 were compared to the deviations measured by two independent observers.

The limits set up for test were not violated.

The absolute difference between paired values (reader MT-200) is less than 0.1 mV.

The total number of differences greater than 0.1 mV is less than or equal to 2% of the total number of measurements.

All tests are passed

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 Brentwood Rhythmscan Precision CS-6000 (K914577) Device.

All tests are passed.

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: K973751
Microvit MT-200
Regulatory Class: II (two)
Product Code: 74 DQK
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 973751

Device Name: Holter Evaluation Software MT-200

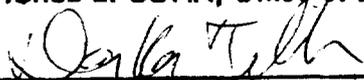
Indications For Use:

The ECG Holter evaluation software, MT-200, is an analysis software used for the analysis and evaluation of Holter ECG recordings. The Holter recordings are used 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 K 973751

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-90)