SCHILLER AG
Altgasse 68, Postfach
CH-6341 Baar
Tel: +41 (41) 766 42 42
Fax: +41 (41) 761 08 80

MWST Nr. 212858
sales@schiller.ch
buying@schiller.ch
http://www.schiller.ch

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The Art of Diagnostics

K101619

NOV 12 2010

510 (k) Summary of Safety and Effectiveness

according to 21 CFR 807.92

A1 Address

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Contact Name:	Serkan Sezer
Tel:	+ 41 41 766 4252
Date:	28.th May 2010

A2 Device Name

1. Trade Name:	Welch Allyn 1500 Patient Monitor
2. Common Name:	Monitoring System

A3 Legally Marketed Device

Legally Marketed Device to which this submitted device is compared:

Parameters – 12-lead Rest-ECG Analysis

The 12-lead Rest-ECG Analysis algorithm used in the 1500 Patient Monitor has been FDA-cleared in the SCHILLER ARGUS LCM K053207).

Parameters – Temperature

The Patient Temperature parameter circuitry and algorithm used in theWelch Allyn 1500 Patient Monitor has been FDA-cleared in the SCHILLER ARGUS LCM K053207).

Parameters – Respiration

The Respiration parameter circuitry and algorithm used in the 1500 Patient Monitor has been FDA-cleared in the SCHILLER ARGUS LCM K053207).

Parameters –NIBP and Invasive Blood Pressure

The Not Invasive Blood Pressure parameter circuitry and algorithm used in the 1500 Patient Monitor has been FDA-cleared in the SCHILLER BP-200plus (K063814).

Parameters –Invasive Blood Pressure

The Invasive Blood Pressure parameter circuitry and algorithm used in the 1500 Patient Monitor has been FDA-cleared in the SCHILLER ARGUS LCM K053207).

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Parameters – Temperature

The Patient Temperature parameter circuitry and algorithm used in the 1500 Patient Monitor has been FDA-cleared in the SCHILLER ARGUS LCM K053207).**Parameters – Pulse Oximetry (SpO2)**

The SpO2 parameter circuitry and algorithm used in the 1500 Patient Monitor has been FDA-cleared in the Nellcor Oximax NPB-40 Pulse Oximeter (K051352).

Parameters – ECG Arrhythmia / ST-segment Analysis

The Mortara ECG Arrhythmia and ST-segment analysis algorithm used in the 1500 Patient Monitor has been FDA-cleared in the Datascope Passport 2 Vital Signs Monitor (K020550).

Parameters – end-tidal CO2

The end-tidal CO2 parameter circuitry and algorithm used in the 1500 Patient Monitor has been FDA-cleared in the Oridion Capnostream10 Bedside Monitor (K060065).

A4 Intended Use

The Welch Allyn® 1500 Patient Monitor patient monitoring unit is designed for the monitoring of vital parameters such as ECG, SpO2, etCO2, non invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature and respiration of a patient.

- The device is intended to be used by qualified doctors or trained medical personnel.
- The device is not suitable for transport.
- There is no danger for patients with pacemaker.
- The device is intended for the monitoring of one patient at a time.
- The device is not designed for sterile use nor is it designed for outdoor use.
- Do not use this monitor in areas where there is any danger of explosion or in the presence of flammable gases.
- The device is classified CF. It is defibrillation protected when the original accessories are used. However, as a safety precaution when possible, remove the electrodes before defibrillation.
- This product is not designed for direct cardiac application.
- The arrhythmia module is not intended for use with neonatal patients.
- The ST-analysis module is not intended for use with neonatal patients.

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A5 Table of Comparison (1)

			ARGUS LCM		WA1500PM
1	Dimensions:		290x275x180mm [1)]		396 x 284 x 81 mm
2	Weight:		4.6 kg / 9.2lbs [2)]		4.6 kg / 9.2lbs [2)]
3	Environmental Conditions:		Indoor use		Indoor use
4	*Operating temperature*		+10° - 40° C		+10° - 40° C
5	*Storage temperature*		-10° - +50° C		-10° - +50° C
6	*Relative humidity*		25% - 95% (non condensing)		25% - 95% (non condensing)

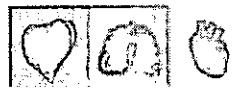
Discussion of Difference:

None of the above difference (1) can be considered as safety relevant difference.

We consider the submitted device to be as safe and effective as the Predicate SCHILLER ARGUS LCM (K 053207) device.

1. Table of Comparison (2)

Argus LCM	*WA1500PM*	*Module*	**Standards**	**Different**
X	X	Safety	IEC 60601-1	Same
-	X	Software	IEC 60601-1-4	Same
X	X	EMC	IEC 60601-1-2	New Standard
X	X	ECG	IEC 60601-1 IEC 60601-2-27	Same
X	X	Monitoring	IEC 60601-2-34 IEC 60601-2-49	Same
X	X	SPO2	EN 9919	New Standard
X	X	NIBP	IEC 60601-2-30	Same
X	X	Temp.	EN 12470-4	Same
X	X	CO2	ISO 21647-1	New Standard
X	X	IBP	IEC 60601-2-34	same



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B1 Non-Clinical Tests

2. Electrical Safety and Reliability:

- IEC 60601-1: General requirements for basic safety and essential performance. Protection Class I Type CF
- IEC 60601-1-4: General requirements for collateral standard: programmable electrical medical systems.
- IEC 60601-1-6: General requirements for safety - collateral standard usability
- IEC 60601-2-27: Particular requirements for the safety of electrocardiographic monitoring equipment
- IEC 60601-2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
- IEC 60601-2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
- IEC 60601-2-49: Particular requirements for the safety of multifunction patient monitoring equipment
- ISO 9919. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

3. Protection Class

- Protection against electric shocks, Class I according to IEC/EN 60601-1 (with internal power)

4. IP- Protection

- This device is not designed for outdoor use (IPX1)

5. EMC

- IEC/EN 60601-1-2 (class A)

6. Additional Requirements

- EN 1060-1 and 3 (non-invasive blood pressure recorders part 1)

7. Conformity

- CE according to directive 93/42/EEC class IIb

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.

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B3 Summary of Performance Testing:

The SCHILLER Welch Allyn 1500 Patient Monitoring and associated accessories have been tested and found to comply with recognized national and international performance, safety and electromagnetic compatibility standards for medical devices and product specifications listed in the SCHILLER Welch Allyn 1500 Patient Monitoring labeling.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of SCHILLER AG, product development procedures. SCHILLER AG Quality System conforms to 21 CFR 820 and is Certified to ISO 9001:2008 and ISO 13485:2003

Conclusion

As stated above, SCHILLER AG conclusion is that the SCHILLER Welch Allyn 1500 Patient Monitor is safe, effective, comply with the appropriate medical device standards and equivalent to the SCHILLER ARGUS LCMK053207; SP02 Module Nelcor K051352; CO2 Module Oridien K072295; ECG Library Mortara K020550; NIBPNodule SCHILLER K063814 all parameters currently on the market.

Baar (Switzerland) 28th May 2010

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

Serkan Sezer

SCHILLER AG

Quality and Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Serkan Sezer
Quality and Regulatory Affairs Manager
SCHILLER AG
Altgasse 68
Baar, Zg
SWITZERLAND 6341

NOV 1 2 2010

Re: K101619
Device Name: Welch Allyn® 1500 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient physiological monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (Two)
Product Codes: MHX
Dated: October 19, 2010
Received: October 20, 2010

Dear Mr. Sezer:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for 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): K101619

NOV 1 2 2010

Device Name: Welch Allyn 1500 Patient Monitor

Indications For Use:

The Welch Allyn 1500 Patient Monitor is an ultra-flat patient monitor designed for neonates, children, adult and paediatric use. It has a LCD screen for comprehensive vital data monitoring.

Mains power supply is used for stationary use. The Welch Allyn 1500 Patient Monitor also provides full vital data monitoring during transport with the built-in battery.

The Welch Allyn® 1500 Patient Monitor patient monitoring unit is designed for the monitoring of vital parameters such as ECG, SpO2, etCO2, non invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature and respiration of a patient.

- The device is intended to be used by qualified doctors or trained medical personnel.
- The device is not suitable for transport.
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- This product is not designed for direct cardiac application.
- The arrhythmia module is not intended for use with neonatal patients.
- The ST-analysis module is not intended for use with neonatal patients.

Baar (Switzerland) 21th July 2010

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

SCHILLER AG
Serkan Sezer

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101619