K101571

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PHILIPS

510(K) SUMMARY

Submitted by:	Witt Biomedical Corporation (a wholly owned subsidiary of Philips Holding USA, Inc.) 305 North Drive, Melbourne Florida 32934
Contact Person:	James Luker Phone: (321) 253-5693 ext 1161 Fax: (321) 253-0372
Date Prepared:	May 28, 2010
Proprietary Name:	Xper Flex Cardio physiomonitoring system , Xper Information Management System
Common Name:	Physiomonitoring System Information System
Classification Name:	21 CFR § 870.2300 74 MWI (for Physiomonitoring System) Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) Class II 21 CFR § 870.1425 74 DQK (for Information system) Computer, Diagnostic, Programmable Class II
Predicate Device(s):	Xper Information Management System- K063840 GE MacLab/CardioLab EP/ComboLab System- K050093 Poise DataEngine- K040969 Siemens AXIOM Sensis- K020440 Alliance Instruments Integrity Patient Monitor- K980688

Device Description:

The Xper Flex Cardio physiomonitoring system and Xper Information Management systems are enhancements of the cleared Xper Information Management system (K063840).

The Xper Flex Cardio physiomonitoring system is used to facilitate invasive investigation of heart and vascular disease when non-invasive indicators warrant such. The Xper Flex Cardio physiomonitoring system may be used to display and analyze surface ECG (electrocardiogram), respiration, invasive pressure, SpO_2 (pulse oximetry), end tidal CO_2 ($ETCO_2$) and non-invasive pressure waveforms; surface body temperature and thermal cardiac output curves. The system is capable of processing/analyzing information such as multi-channel ECG signals and displaying a graphical ST segment map. The Xper Flex Cardio physiomonitoring system makes measurements that assist physicians and other clinicians to evaluate a patient's overall cardiopulmonary performance, conductive system and general vascular status. The Xper Flex Cardio physiomonitoring system is not intended for use in the proximity of magnetic resonance imaging.

The Xper Information Management System is used for acquiring, displaying, trending, storing and transmitting various types of data such as physiologic/hemodynamic, clinical, medical image and other related data. The system is capable of processing/analyzing information such as multi-channel ECG signals, displaying a graphical ST segment map and performing other data management functions such as creating reports. Data may be acquired from and/or sent to other devices such as physiological monitoring systems, information management systems, image acquisition/storage devices and other medical devices.

Intended Use Statement(s):

Xper Flex Cardio Physiomonitoring System- The physiomonitoring system is intended for use by professional healthcare providers for complete physiologic/hemodynamic monitoring, clinical data acquisition, medical image/data processing, and analytical assessment. The system is indicated for use in the following areas: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology and other areas where cardiac monitoring may be required. The system is not intended to be used in the proximity of magnetic resonance imaging. The data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses. Use of the system is not intended where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

The system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet, or may function as a stand-alone device.

Xper Information Management- The information management system is intended for use under the direct supervision of a healthcare practitioner for acquiring, displaying, trending, storing and transmitting various types of data, such as physiologic/ hemodynamic, clinical, medical image and other related data. The system is capable of processing/analyzing information, such as multi-channel ECG signals, and performing other data management functions, such as creating reports. Data may be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

The system is indicated for use in the following areas: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and surrounding areas where access to the information is needed.

The system consists of modules and may be entirely a software offering or a hardware/software offering. It is intended for use on standard computer systems and does not require proprietary hardware. The solution is available as a single module or combination of modules, or may function as a standalone system.

The system is capable of receiving and displaying user-adjustable alarms (both visual and audible) available in the system, which alert the operator to anomalous occurrences and facilitate timely responses. Use of the system is not intended where unattended patient

monitoring is desired, or in situations where arrhythmia detection is required.

The system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet, or may function as a stand-alone device.

Technological Characteristics:

The enhanced device has the same technological characteristics as the legally marketed predicate device(s). The enhancements consist of these primary changes:

- Introduction of trade name Xper Flex Cardio Physiomonitoring System as well as names for devices and software components.
- Introduction of "re-designed" Front-End & Patient Care Console devices which include a change from AC power to DC power.
- Introduction of separate Intended Use statements for the monitoring aspects (Xper Flex Cardio Physiomonitoring System) and the information management aspects (Xper Information Management System)
- Change from CAS NE Non-Invasive Blood Pressure (NIBP) module to CAS ND+ Non-Invasive Blood Pressure (NIBP) module.
- Change from Respironics $ETCO_2$ sensors to Philips branded $ETCO_2$ sensors.
- Introduction of new software modules:
  - Hemodynamic Software Module
  - Hemodynamic Control Software
  - Electrophysiology Logging & Reporting (EP Logging & Reporting)
  - Web Portal
  - Patient Status Viewer (Whiteboard)
  - Connectivity to cleared devices
- Increase from 12 lead ECG (maximum) to 16 Lead (maximum)
- Introduction of Philips ECG algorithm (individually cleared in K073376)
- Upgrades in hardware and software (custom and off the shelf) to facilitate integration of the latest technology.
- Introduction of connectivity to other cleared devices.
- Introduction of ability to run server functions in a virtual software environment.
- Introduction of alarm silencing functionality

Performance Data: The Performance Testing as well as the hazard analysis for the Xper Flex Cardio physiomonitoring system and Xper Information Management System provides objective evidence that it is substantially equivalent to the predicate Xper Information Management system and other listed predicate devices.

Performance Testing:

- Master Test Plan(s)

Voluntary Standards

General Requirements for Safety

- IEC 60601-1
- IEC 60601-1-1
- EN 60601-1-2
- IEC 60601-2-30
- IEC 60601-2-49

Substantial Equivalence The Xper Flex Cardio physiomonitoring system and Xper Information Management System are substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) number	Clearance date:
Xper Information Management System	Witt Biomedical Corporation (a wholly owned subsidiary of Philips Holding USA, Inc.)	K063840	02/06/2007
MacLab/CardioLab EP/ComboLab System	GE Medical Systems	K050093	05/13/2005
Poise DataEngine	Poise Technology Corp.	K040969	06/08/2004
AXIOM Sensis	Siemens Healthcare	K020440	12/03/2002
Integriti Patient Monitor	Alliance Instruments	K980688	03/16/1999

Conclusion The results of the safety and performance testing demonstrate that the Xper Flex Cardio physiomonitoring system and the Xper Information Management System are as safe and effective as the predicate device(s) and perform as well as the predicate device(s).

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

Witt Biomedical Corporation
c/o Mr. James Luker
Q & R Engineer
305 North Drive
Melbourne, FL 32934

OCT 26 2010

Re: K101571
Trade/Device Name: Xper Flex Cardio Physiomonitoring System and Xper Information Management device
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (two)
Product Code: MWI, DQK
Dated: September 28, 2010
Received: September 29, 2010

Dear Mr. Luker:

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 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: K101571

OCT 26 2010

Device Name: Xper Flex Cardio physiomonitoring system

Indications for Use:

The physiomonitoring system is intended for use by professional healthcare providers for complete physiologic/hemodynamic monitoring. The system may be used to display and analyze surface ECG (electrocardiogram), respiration, invasive pressure, pulse oximetry (SpO_2), end tidal CO_2 ($ETCO_2$), fractional flow reserve (FFR), non-invasive blood pressure (NIBP), surface body temperature and thermal cardiac output. The system also provides for clinical data acquisition, medical image/data processing, and analytical assessment. The system is indicated for use in the following areas: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology and other areas where cardiac monitoring may be required. The system is not intended to be used in the proximity of magnetic resonance imaging. The data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses. Use of the system is not intended where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

The system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet, or may function as a stand-alone device.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101571

Indications for Use

510(k) Number: K107571

Device Name: Xper Information Management System

Indications for Use:

The information management system is intended for use under the direct supervision of a healthcare practitioner for acquiring, displaying, trending, storing and transmitting various types of data, such as physiologic/ hemodynamic, clinical, medical image and other related data. The system is capable of processing/analyzing information, such as multi-channel ECG signals, and performing other data management functions, such as creating reports. Data may be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

The system is indicated for use in the following areas: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and surrounding areas where access to the information is needed.

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The system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet, or may function as a stand-alone device.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)