K063840
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Section 5 – 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
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FEB 6 2007

Date Prepared: December 22, 2006

Proprietary Name: Xper Information Management/Physiomonitoring 5 and/or Vascular 5 system, Patient Care Console and Central Station, and ECG Management system

Common Name: Physio-monitoring System

Classification Name: 21 CFR § 870.2300 74 MWI
Monitor, Physiological, Patient (without Arrhythmia detection or alarms)
Class II

Predicate Device: CALYSTO Series IV, Patient Care Monitor and Central Station, and ECG Management System K033030

Device Description: The Xper Information Management device is intended to be used for complete physiologic/hemodynamic monitoring and information gathering as well as medical image review through links to cleared devices. It facilitates clinical data acquisition and analytical assessment for cardiac catheterization, invasive radiology and electrophysiology laboratories.

Intended Use: Xper Information Management/Physiomonitoring 5 and/or Vascular 5 system, Patient Care Console and Central Station is intended for complete physiologic/hemodynamic monitoring, clinical data acquisition, medical image/data processing, and analytical assessment for cardiac catheterization, invasive radiology and electrophysiology laboratories. Its users, responsible to interpret the data made available, will be professional health care providers. Xper Information Management/Physiomonitoring 5 and/or Vascular 5 system, Patient Care Console and Central Station provides the ability to transmit patient data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

Use of Xper Information Management/Physiomonitoring 5 and/or Vascular 5 system, Patient Care Console and Central Station is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required.

The Xper Information Management Central Station and Patient Care Consoles are intended for complete physiologic monitoring, clinical data acquisition, medical image processing and analytical assessment within any healthcare environment. Its users, responsible to interpret the data made available, will be professional health care providers. User adjustable alarms (both visual and audible), alert the operator to anomalous occurrences and facilitate timely responses.

Use of Xper Information Management Central Station and Patient Care Console is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required.

The Xper ECG Management System is intended for receiving and storing resting, stress and holter ECG data from source devices. ECG data is stored, unaltered, in its original format, and made available for review and procedural report generation purposes. Xper ECG Management System does not provide interpretive functions, but does store interpretive statements generated by the source device in an integrated and expandable database. Its users, responsible to interpret the data made available, will be professional health care providers. Xper ECG Management system provides the ability to transmit ECG data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

Technological Characteristics:

The modified device has the same technological characteristics as the legally marketed predicate device (K033030). The modifications consist of these primary changes:

- Introduction of trade name
- GUI updates.
- Upgrades in hardware and software (custom and off the shelf) to facilitate integration of the latest technology.

Verification, Validation, and Testing:

The Performance Testing as well as the Hazard analysis for the Xper Information Management system provides objective evidence that it is substantially equivalent the predicate CALYSTO Series IV system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Witt Biomedical Corp.
c/o James Luker
305 North Drive
Melbourne, FL 32934

FEB 6 2007

Re: K063840
Trade Name: Physio-monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: December 22, 2006
Received: December 26, 2006

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 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number:

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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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number: K063840

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510(k) Number:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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