JUN 0 4 2002

K013032

510(k) Summary

Date prepared: May 31, 2002
Name of contact person: Scott Pease
Device trade name: VERICIS Physiolog
Common name: Cardiac Cath Lab Physiologic Data Recording System
Classification name:
Predicate substantially equivalent devices: K950436 Witt Biomedical Series IV Physiomonitoring System
Device description and intended use: VERICIS Physiolog monitors, measures, and/or records physiologic data and patient images from a patient undergoing a cardiac catheterization procedure. VERICIS Physiolog is intended for use in hospital cardiac catheterization laboratories.
Predicate device specifications comparison:

Feature	**Camtronics VERICIS Physiolog**	**Witt Biomedical Central Station Monitoring System K973474 and Series IV Physiomonitoring System K950436**
Signals transduced	12-lead EKG (heart rate) Respiratory rate 4 invasive pressures NIPB/SpO2	12-lead EKG (heart rate) Respiratory rate Invasive pressures NIPB/SpO2
Cardiac output	Yes	Yes
Display screens	CRT color monitor	CRT color monitor
HIS Interface	Yes, optional	Yes, optional
Digital Imaging System Interface	Yes	Yes
Computer system	PC-based off-the-shelf hardware; Windows 2000	PC-based off-the-shelf hardware, Windows
User interface	Keyboard, mouse	Keyboard, mouse
Automated hemodynamic data analysis functions	Continuous systolic, diastolic, and mean pressure, wedge, end diastolic pressure. Gradients by pullback or differential pressure. Valve area calculations. Automatic beat selection. Resistance, shunt, and flow calculations. Assumed oxygen consumption. AJI calculations may be displayed for verification or edit.	Instantaneous hemodynamic results and on-line QCA
Automatic time stamped log of catheterization events and procedures	Menu selection from customized protocols, automatic entries, and free text. Correlated by time to waveform recordings and measurements. Also menu selections for emergency protocols and medications.	Same

Performance data: The VERICIS Physiolog software was tested using physiologic simulators. Various types of ECG aberrations, rates, amplitudes, and deviations were used for validation of R-Wave detection for the rate meter and timing measurements related to pressure analysis. Multiple pressures were simulated under various conditions to validate the pressure and valve analyses. Multiple oxygen saturations were entered to validate hemodynamic calculations. Multiple erroneous and/or incongruous entries were made in data entry locations to validate data entry restrictions. Multiple cases were created to validate data integrity. All command buttons were tested for their appropriate response. Multiple reports were generated to validate the report generation functions. The software responded appropriately in the tests described. After assembly is completed, each unit undergoes final product testing. Patient isolation and leakage current tests are to be performed on each unit prior to packaging for shipment.

Conclusions drawn from clinical and nonclinical test data: Not required for determination of substantial equivalence for this class of device.

Substantial equivalence summary: The Camtronics VERICIS Physiolog System is a comparable type and substantially equivalent to a legally marketed predicate device. The intended use of the Camtronics VERICIS Physiolog System is the same as that of the predicate device "Series IV Physiomonitoring System" marketed by Witt Biomedical. No new safety or effectiveness issues are raised with the Camtronics VERICIS Physiolog System. The subject device has substantially equivalent technological characteristics, features, specifications, materials, modes of operation, and intended uses as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Camtronics Medical Systems
c/o Mr. Scott J. Pease
Director, Quality Assurance and Regulatory Affairs
900 Walnut Ridge Drive
P.O. Box 950
Hartland, WI 53029

Re: K013032
Trade Name: Vericis Physiolog
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: March 27, 2002
Received: March 29, 2002

Dear Mr. Pease:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: __ Camtronics Medical Systems _____ Page 1 of 1

510(k) Number (if known): ____ K013032 _____

Device Name: ___ VERICIS Physiolog _____

Indications For Use:

VERICIS Physiolog monitors, measures, and/or records physiologic data and patient images from a patient undergoing a cardiac catheterization procedure. VERICIS Physiolog is intended for use in hospital cardiac catheterization laboratories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013032

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use X
(Per 21 CFR 801.109)