K051649

Camtronics®
MEDICAL SYSTEMS

AUG 2 - 2005

Summary of Safety and Effectiveness for VERICIS Cardiovascular Image and Information System

A. Submitter

Camtronics Medical Systems
900 Walnut Ridge Drive
Hartland, Wisconsin 53029
Telephone: 262-367-0700
Contact person: Steve Krueger
Date prepared: June 1, 2005

B. Device

Trade Name:	VERICIS Cardiovascular Image and Information System
Common Name:	Picture Archiving and Communications Systems and Workstations
Regulation Number:	21CFR 892.2050
Regulation Name:	System, Image Processing, Radiological
Regulation Class:	II
Product Code:	LZZ

C. Predicate Devices

McKesson Horizon Medical Imaging (K043146)

D. Device Description

The VERICIS is an integrated cardiovascular information system classified as a picture archiving and communications system. The VERICIS is a modification of the Camtronics Analytical Review Station (K955519) and the Echocardiography System (K992259) to accept multiple modalities. The VERICIS combines modular software applications and third party "off-the-shelf" software on standard computer workstations and servers running the specified Microsoft Windows operating systems.

E. Intended Use

VERICIS is a system intended to be used to acquire, store, print, transfer, and archive clinical information from Camtronics and other vendors systems including images, Hemodynamic studies and reports, measurements (via import

from DICOM Structured Reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data. VERICIS is intended to allow users to review diagnostic and non-diagnostic quality images, annotate studies, perform digital subtraction on images, to perform quantitative measurements on images (including but not limited to quantitative coronary analysis, left ventricular analysis, time, area, length, velocity, angle, volume, and velocity-time integrals), to generate physician-generated clinical reports (via structure reporting and template based tools), and to store this information in a database.

- VERICIS is software comprised of modules that perform under standard "off-the-shelf" personal computers and servers running the Microsoft Windows 2000/2003/XP operating systems.
- VERICIS is image data storage and display software that accepts DICOM (Digital Imaging and Communications in Medicine) image data files from multiple modalities. It accepts text data using other standards-based formats including but not limited to HL7 and XML.
- VERICIS is an Internet/Intranet network system that is designed for small and large, multi-user environments. The VERICIS network structure (including server and workstations) provides for the system's database management, storage, printing, and all DICOM/HL-7 interface services.

F. Substantial Equivalence

The VERICIS Cardiovascular Image and Information system employs the same fundamental scientific technology as the McKesson Medical Imaging Company, Horizon Medical Imaging (K043146), the predicate device.

G. Technological Characteristics

The VERICIS combines modular software applications and third party off-the-shelf software on standard computer workstations and servers running the Microsoft Windows 2000/2003 and XP operating systems. When the VERICIS software is loaded on the specified IBM PC compatible computers, hardware and peripherals the resulting system will act and perform similar to the McKesson Horizon Imaging system to receive, transmit, store, retrieve, display print and process digital medical images, digital medical video, and associated medical information from various medical imaging systems.

H. Conclusions

Camtronics Medical Systems has demonstrated through its comparison of performance with the predicate devices that the VERICIS is equivalent to the Horizon Medical Imaging system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 - 2005

Mr. Steve Krueger
Director of Regulatory
Affairs/Quality Assurance
Camtronics Medical System
900 Walnut Ridge Drive
HARTLAND WI 53029

Re: K051649
Trade/Device Name: VERICIS Cardiovascular Image and Information System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 20, 2005
Received: June 21, 2005

Dear Mr. Krueger:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051649

Indications for Use

510(k) Number (if known):

Device Name: Camtronics Medical Systems VERICIS Cardiovascular Image and Information System

Indications For Use: VERICIS is a system intended to be used to acquire, store, print, transfer, and archive clinical information from Camtronics and other vendors systems including images, Hemodynamic studies and reports, measurements (via import from DICOM Structured Reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data. VERICIS is intended to allow users to review diagnostic and non-diagnostic quality images, annotate studies, perform digital subtraction on images, to perform quantitative measurements on images (including but not limited to quantitative coronary analysis, left ventricular analysis, time, area, length, velocity, angle, volume, and velocity-time integrals), to generate physician-generated clinical reports (via structure reporting and template based tools), and to store this information in a database.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, Radiological Devices
510(k) Number K051649