DEC 17 2002

510(k) SUMMARY

Date Prepared: 21 June 2002

Submitter
Problem Solving Concepts, Inc.
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Indianapolis, IN 46250

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Registration number: 1836517

Contact Person
Thomas M. McClelland (317) 594-7431

Device Name
Trade Names: ProSolv® CardioVascular, ProSolv® CardioVascular Viewer, ProSolv® CardioVascular Analyzer, and ProSolv® CardioVascular Server
Common Name: Picture Archiving and Communications Systems (PACS) Components
Class: No formal classifications have been issued for PACS components.
Performance Standards: No performance standards have been issued for PACS components under the authority of section 514.

Device Description

The ProSolv® CardioVascular software operates on a PC computer using the Windows 95 or later operating system. ProSolv® CardioVascular Viewer allows the user to view medical images acquired from digital-imaging instruments, track examinations and patient data with a database, and view reports. The software can display DICOM images and most non-DICOM images. ProSolv® CardioVascular Analyzer includes all the functionality of the Viewer plus routine and stress echo regional wall motion analysis, qualitative and quantitative image evaluation, report generation, and customizable reports, measurements, and comment lists. Each of the products can be packaged with the optional ProSolv® CardioVascular Server capability to allow remote database access over a network.

Indications For Use

ProSolv® CardioVascular is intended for use by doctors and non-physicians (e.g., sonographers, technicians, nurses) who are affiliated with medical labs that use images obtained from digital-imaging DICOM instruments (echo, vascular, nuclear cardiology, cardiac catheterization, MRI, etc.) The ProSolv® CardioVascular image management and reporting system is software that operates on standard PC equipment using Windows 95 or later operating system. ProSolv® CardioVascular provides the functionality for archiving, viewing, measuring, analyzing, and reporting digital studies generated by digital-imaging instruments from a multitude of manufacturers. The software is available in several configurations: Administrator

(report viewing, edit patient demographic information), Viewer (image and report viewing, basic measurements), and Analyzer (Viewer features plus measurements, qualitative assessment, and report creation and design). The software can be used in a variety of network configurations ranging from a stand-alone workstation to a network of workstations connected through TCP/IP networking to a ProSolv® DICOM Server. The DICOM Server permits studies to be transferred from DICOM compatible imaging instruments directly to a ProSolv® database using TCP/IP.

General Safety and Effectiveness Concerns

The device labeling and manual provide operating instructions for the safe and effective use of ProSolv® CardioVascular software. The display, storage, retrieval, and analysis of information provide a minor level of hazard concern.

Substantial Equivalence

ProSolv® CardioVascular is substantially equivalent to the ProSolv® Echo products that are currently on the market. While there are some feature differences between the ProSolv device and the equivalent device, these differences do not affect the safety or effectiveness of the new device.

The ProSolv CardioVascular products have expanded on the ProSolv Echo products to include additional medical disciplines. As the image viewer was already a generic DICOM viewer, few changes were made in this area other than additional viewer features. The primary area of changes necessary to incorporate other medical fields was the addition of new measurements and reports. The customizing features of the software were already present in ProSolv Echo, so vascular measurements had to be added and vascular reports had to be developed with the aid of a beta site. With ProSolv CardioVascular being a general image viewer and reporting system, and with its advanced customizing features, the product can be expanded into other areas as well. This requires creating a list of measurements if needed, the necessary reports and appropriate comment files. This flexibility contributes to the effectiveness of the device, without compromising the safety.

Conclusions

With ProSolv® CardioVascular digital medical images, from virtually any digital-imaging instrument available today, can be reviewed, measured, analyzed, reported, databased, and archived. The software can read DICOM images and most non-DICOM images. ProSolv® CardioVascular Server allows for remote access to a database located on a server.

The ProSolv® CardioVascular device meets applicable standards and several voluntary standards. The primary difference between the current ProSolv device and the equivalent device is in the expanded indications for use. The core program is basically the same, with some added features for the viewer, analyzer and reporting functions. These differences do not adversely affect the safety or effectiveness of the new device. Based on the comparison between the ProSolv® CardioVascular device and the legally marketed device, all indications are that the ProSolv® CardioVascular device is substantially equivalent to ProSolv® Echo.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

Problem Solving Concepts, Inc
c/o Mr. Thomas M. McClelland
Product Engineer
8020 Castleway Drive, Suite 120
Indianapolis, IN 46250

Re: K023112
Trade Name: ProSolv® CardioVascular
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: September 16, 2002
Received: September 19, 2002

Dear Mr. McClelland:

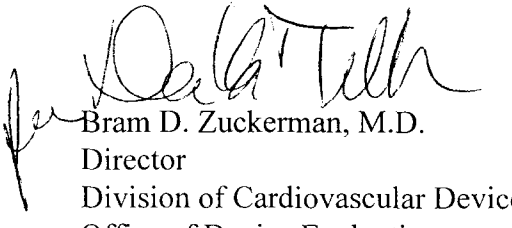
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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,



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

Enclosure

510(k) Number (if known):_____

Device Name: ProSolv CardioVascular

Indications For Use:

ProSolv® CardioVascular is intended for use by doctors and non-physicians (e.g., sonographers, technicians, nurses) who are affiliated with medical labs that use images obtained from digital-imaging DICOM instruments (echo, vascular, nuclear cardiology, cardiac catheterization, MRI, etc.) The ProSolv® CardioVascular image management and reporting system is software that operates on standard PC equipment using Windows 95 or later operating system. ProSolv® CardioVascular provides the functionality for archiving, viewing, measuring, analyzing, and reporting digital studies generated by digital-imaging instruments from a multitude of manufacturers. The software is available in several configurations: Administrator (report viewing, edit patient demographic information), Viewer (image and report viewing, basic measurements), and Analyzer (Viewer features plus measurements, qualitative assessment, and report creation and design). The software can be used in a variety of network configurations ranging from a stand-alone workstation to a network of workstations connected through TCP/IP networking to a ProSolv® DICOM Server. The DICOM Server permits studies to be transferred from DICOM compatible imaging instruments directly to a ProSolv® database using TCP/IP.

(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 K023112

(Optional Format 3-10-98)

X Prescription Use