FEB 2 2000

Problem Solving Concepts, Inc.
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510(k) SUMMARY

K993750

Date Prepared: 21 October 1999

Submitter

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Registration number: Form FDA-2891 has been submitted

Contact Person

Thomas M. McClelland (317) 848-7431
or Thomas D. Feigenbaum (if TMM not available)

Device Name

Trade Names: ProSolv® Echo, ProSolv® EchoViewer, ProSolv® EchoViewer SE, ProSolv® EchoAnalyzer, and ProSolv® EchoServer

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® Echo software operates on a PC computer using the Windows 95/98/NT operating system. ProSolv® EchoViewer allows the user to view echocardiographic and cardiac catheterization images from a variety of sources, track examinations and patient data with a database, and view reports. DICOM images and most non-DICOM images can be read by the software. ProSolv® EchoViewer SE adds to the EchoViewer by including Stress Echo regional wall motion analysis, qualitative image evaluation with a customizable comment list, and report generation. ProSolv® EchoAnalyzer includes all the functionality of EchoViewer SE, plus quantitative image evaluation, routine regional wall motion scoring, and customizable reports and measurements. Each of the products can be packaged with the optional ProSolv® EchoServer capability to allow remote database access via the Internet.

Indications For Use

ProSolv® Echo is stand-alone software that operates on standard PC equipment. The device is available in three configurations (EchoViewer, EchoViewer SE, and EchoAnalyzer) and is intended for use by echocardiographic labs. ProSolv® EchoViewer is also intended for use by cardiac catheterization labs. ProSolv® Echo incorporates the latest technology in archiving, viewing, measuring, analyzing, and reporting digital echocardiographic studies generated by a multitude of ultrasound

manufacturers. The device configurations can be packaged with ProSolv® EchoServer to extend the capabilities for laboratories wanting to access a remote, secure database and archive images over the Internet.

General Safety and Effectiveness Concerns

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

Substantial Equivalence

ProSolv® Echo is substantially equivalent to the following products that are currently on the market: HP 5500 Sonos (EnConcert software) and Digisonics' Doctor Review System (DigiView System). As the equivalent devices can contain hardware and software components, the ProSolv device is being compared only to the software components. While there are some technological differences between the ProSolv device and the equivalent devices, these differences do not affect the safety or effectiveness of the new device.

The primary difference between the ProSolv® EchoViewer and the two SE devices is in the image formats that are read and stored. The ProSolv software seems to have more flexibility in compression options, which adds to the safety and effectiveness of the device. Users have several options to try on their systems before deciding on a routine compression method.

The primary difference between the EchoAnalyzer and the equivalent devices is in the equations and measurements area. ProSolv has the unique ability for users to view the equations being used to make the calculations based on the measurements. In addition, new measurements and equations can be created to adapt to a laboratory's routine measurements. ProSolv software limits these modifications to only those users with the proper security level access. This flexibility contributes to the effectiveness of the device, without compromising the safety.

Conclusions

With ProSolv® Echo digital echocardiographic images, from virtually any digital ultrasound instrument available today, can be reviewed, measured, analyzed, reported, databased, and archived "off-line". The software can read DICOM images and most non-DICOM images. ProSolv® EchoServer allows for remote access to a database located on a server.

The ProSolv® Echo device meets applicable standards and several voluntary standards. While there are some technological differences between the ProSolv device and the equivalent devices, these differences do not affect the safety or effectiveness of the new device. Based on the comparison between the ProSolv® Echo device and the legally marketed devices, all indications are that the ProSolv® Echo device is substantially equivalent to HP Sonos 5500 (EnConcert) and Digisonics' Doctor Review System (DigiView).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2000

Thomas M. McClelland
Project Engineer
Problem Solving Concepts, Inc.
1980 E. 116th Street, Suite 220
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Re: K993750
ProSolv® EchoViewer, ProSolv® EchoViewer SE, ProSolv® EchoAnalyzer, ProSolv® EchoServer, and ProSolv® Echo
Dated: November 2, 1999
Received: November 5, 1999
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. McClelland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K993750

DEVICE NAME: ProSolv EchoViewer, EchoViewer SE, and EchoAnalyzer

INDICATIONS FOR USE:

ProSolv® Echo is stand-alone software that operates on standard PC equipment. The device is available in three configurations (EchoViewer, EchoViewer SE, and EchoAnalyzer) and is intended for use by echocardiographic labs. ProSolv® EchoViewer is also intended for use by cardiac catheterization labs. ProSolv® Echo incorporates the latest technology in archiving, viewing, measuring, analyzing, and reporting digital echocardiographic studies generated by a multitude of ultrasound manufacturers. The device configurations can be packaged with ProSolv® EchoServer to extend the capabilities for laboratories wanting to access a remote, secure database and archive images over the Internet.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-9

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993750