

JUN 30 2003



### 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

May 5, 2003

Submitter's Information: 21 CFR 807.92(a)(1)

Medison Co. Ltd.  
Medison Venture Tower, 997-10  
Daechi-dong, Kangnam-gu,  
Seoul 135-280, Korea

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: *SonoView Pro*<sup>TM</sup> by Medison Co. Ltd.  
Common Name: Picture Archiving Communications System  
Device Classification: 892.2050  
Name: System, Image Processing

Predicate Device: 21 CFR 807.92(a)(3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K022692
Device Name	VoxelPlus <sup>TM</sup> PACS
Applicant	Mevisys Co. Ltd. EE&CS Bldg. Room 4203, KAIST 373-1 Guseong-dong Yuseong-gu Daejeon 305-701 Korea
Product Code	90 LLZ
Date Received	08/13/2002
Decision Date	10/11/2002

Device Description: 21 CFR 807.92(a)(4)

*SonoView Pro*<sup>TM</sup> is an Internet based software picture archiving and communications system that provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. *SonoView Pro*<sup>TM</sup> includes features to access and manage medical imaging studies from ultrasound (US), cat-scan (CT), magnetic radiography (MR), nuclear medicine (NM), computerized radiography (CR), digital radiography (DR), digital x-ray (DX), x-ray angiography (XA), PET scan (PT), and other imaging modalities.



*SonoView Pro™* is deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows 2000/XP). The system does not produce any original medical images. All images located on *SonoView Pro™* have been received from DICOM compliant imaging modalities and/or PACS components or systems. *SonoView Pro™* provides the advanced process functions, such as :

- Supports the freehand scanning, 3D image acquisition, and 3D reconstruction.
- Acquires images from ultrasound system in real time.
- Supports the ultrasound image storage and ultrasound multi-frame image storage.
- Supports the GUI functions: zoom, pan, pseudo-color setting, threshold setting, Gamma correction, and thumbnail.
- Provides the DICOM query and retrieve services (images and presentation states).
- Displays the cut planes of 3D image along the long axis or the short axis.
- Provides 3D rendering modes: MIP, X-ray, translucent, surface, slicing, and 3D cine.
- Supports distance/area/angle measurements.
- Supports Tele-medicine (audio, video, and text) between regional medicine center and remote clients.

Indications for Use: 21 CFR 807 92(a)(5)

*SonoView Pro™* by Medison Co. Ltd. is a software application for the for the display and 3D visualization of medical image data derived from various sources (i.e. Ultrasound, CT scanners, MRI scanners). Images and data can be acquired, stored, communicated, processed, printed, rendered, and displayed within the system and or across computer networks at distributed locations. Typical users of this system are trained professionals, including physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is a software application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

- The 510(k) Pre-Market Notification for *SonoView Pro™* contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.
- The device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
- The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 30 2003

Medison Co., Ltd.  
% Mr. Ned Devine  
Responsible Third Party  
Entela, Inc.  
3033 Medison Ave. SE  
GRAND RAPIDS MI 49548

Re: K031886  
Trade/Device Name: SonoView Pro™  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: June 13, 2003  
Received: June 18, 2003

Dear Mr. Devine:

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 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.

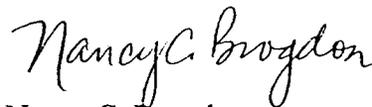
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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) you may obtain. 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,



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

Enclosure



(Indications for Use Form)

510(k) Number:

Device Name:

*SonoView Pro™* by Medison Co. Ltd.

Indications for Use:

*SonoView Pro™* by Medison Co. Ltd. is a software application for the for the display and 3D visualization of medical image data derived from various sources (i.e. Ultrasound, CT scanners, MRI scanners). Images and data can be acquired, stored, communicated, processed, printed, rendered, and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*David A. Seymour*

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number KA31886