K053306

510(k) Summary

APR 19 2006

Submitter Information
OnDemandSoft
501,Tower2,DIP,2139
Daemyung7-Dong,Nam-gu, Daegu, Korea

Contact
Eunmi Chae
Phone: 82-53-652-9764
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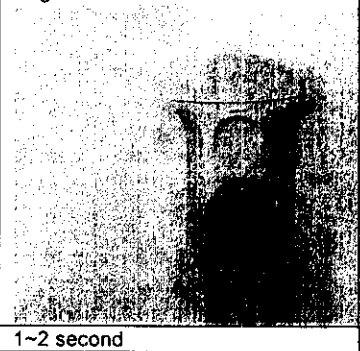
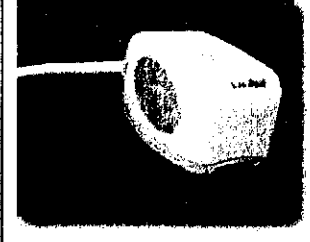
Date Prepared
January 23, 2006

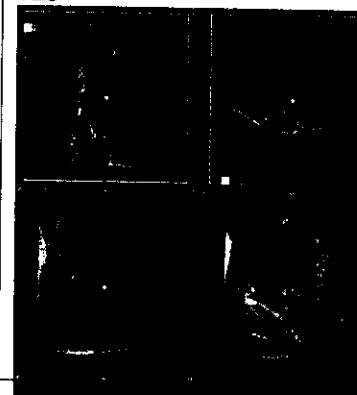
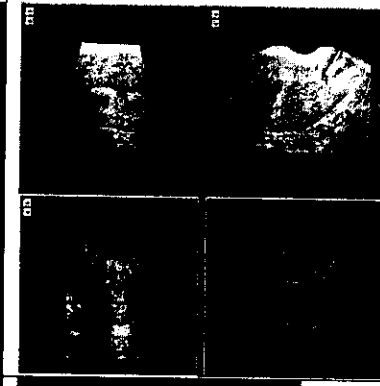
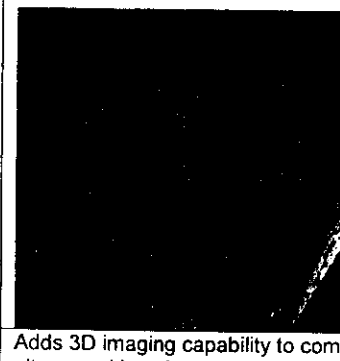
Product Name
Trade name: iView
Classification Name: Ultrasonic pulsed echo imaging system.
Medical Specialty: Radiology
Product Code: IYO
Regulation Number: 892.1560
Device Class: 2

Predicate Device

The iView is substantially equivalent to the SonoReal system marketed by Biomedicom under K023473.

A comparison of devices is provided below:

	OnDemandSoft Co., Ltd (iViewLiveSystem)	BIOMEDICOM (Isreal - SonoReal) (k023473)
1. Scanning Time	2 ~ 6 second	Few Second
2. Scanning Method	Parallel, Fan-Like	Parallel, Fan-Like
3. Sensor 3-1. Sensor Type 3-2. Sensor Installation	Angular Sensor 	Positional Sensor 
4.	1~2 second	Few second

Reconstruction Time		
5. 3D Reconstruction Process	a. Press Foot Switch b. Scan 2D image c. Release Foot Switch d. 3D image is shown e. edit 3D image f. Record complete image on CD / print out / save in HDD	a. Press a mouse button b. Scan 2D image c. Press a mouse button again d. 3D image is shown e. edit 3D image
5. Provided Editing Tools • Rotate • Front Cut Plane • Threshold • Contrast(Control Brightness) • Zoom (Control Magnification) • Panning (Move Image) • Multi Planner View (Shows 4 plane view)	YES YES YES YES YES YES YES 	YES YES YES YES YES YES YES 
6. Result 3D Image 6-1. Fetal Face 6-2. Fetal Whole Body		 
7. Basic Function	Adds 3D imaging capability to commercial 2D ultrasound imaging systems	Adds 3D imaging capability to commercial 2D ultrasound imaging systems
8. Hardware	Pentium IV 2.4 GHZ	Pentium III 833 MHZ
	Frame Grabber (VHS/S-VHS Input)	Frame Grabber (VHS/S-VHS Input)
	Video Out	Video Out
	Foot Pedal	Handheld Controller
9. Software	Volume data acquisition w/frame	Volume data acquisition w/frame grabbing of

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

OnDemandSoft Co., Ltd.
% Mr. Ian P. Gordon
Senior Vice President
EmergoGroup, Inc.
2519 McMullen Booth Road
Suite 510-295
CLEARWATER FL 33761

Re: K053306
Trade/Device Name: OnDemandSoft iView
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: February 28, 2006
Received: March 1, 2006

Dear Mr. Gordon:

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

Indications for Use

510(k) Number (if known): K053306

Device Name: OnDemandSoft iView

Indications for Use:

The iView™ is intended to be used by or under the direction of qualified medical personnel during prenatal monitoring, to visualize fetal features in a reconstructed 3D image that they may wish to exam more closely during routine 2D fetal diagnostic ultrasound imaging examinations, and to assist patient's understanding in communicating diagnostic results in a form that may be more easily understood. It does not provide quantitative measurements or diagnostic interpretations.

The subject device may only be used in an adjunctive capacity with standard diagnostic ultrasound imaging techniques and that no clinical decisions or diagnostic interpretations should be made based solely on the use of this device.

3D image reconstructed from this software is referring use only and is not responsible for any diagnosis.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053306