

JUN 20 2007

K071232



Jan. 29<sup>th</sup>, 2007

## Special 510(k) Summary

Image-Arena Platform 3.x  
Research-Arena Platform 2.x  
Echo-Com 3.x  
Image-Com 3.x  
4D Cardio-View 2.x  
4D LV-Analysis 2.5x  
4D RV-Function 1.x  
4D MV-Assessment 1.x  
4D LV-Function 2.x

### Owner's Name and Address

TomTec Imaging Systems GmbH  
Edisonstrasse 6  
D-85716 Unterschleissheim

### Contact Person

Inge Scheidt  
QM & RA Manager  
Phone ++49-89-32175-515  
Fax ++49-89-32175-750

### Common, Classification & Proprietary Names

Common Name: Various Ultrasound Image Analysis Software &  
System

Classification Name: Ultrasonic Pulsed Echo Imaging System

Proprietary Name(s): Image-Arena and Research-Arena Applications

Image-Arena Platform 3.x  
Research-Arena Platform 2.x  
Echo-Com 3.x  
Image-Com 3.x  
4D Cardio-View 2.x  
4D LV-Analysis 2.5x  
4D RV-Function 1.x  
4D MV-Assessment 1.x  
4D LV-Function 2.x



**Predicate Device**

TomTec      K040546      Image-Arena Applications Research-Arena Applications

**Device Description**

The hardware requirements are based on an Intel Pentium high performance computer system and Microsoft® Windows XP Professional™ or Microsoft® Windows 2000 Professional™ Operating System standards.

The Image-Arena/Research-Arena Applications are a software tool package designed for analysis, documentation and archiving of ultrasound studies in multiple dimensions. The Image-Arena/Research-Arena Applications software tools are modular structured and consist of different software modules, combining the advantages of the previously FDA 510(k) cleared TomTec software product line Image-Arena Applications and Research-Arena Applications. The different modules can be combined on the demand of the users to fulfil the requirements of a clinical researcher or routine oriented physician.

The new Image-Arena/Research-Arena Applications offer features to import different digital 2D, 3D and 4D (dynamic 3D) image formats based on defined file format standards (DICOM-, HPSONOS-, GE-, TomTec- file formats) as well as analogue video acquisition in one system, thus making image analysis independent of the ultrasound-device or other imaging devices used.

Offline measurements, documentation in standard report forms, the possibility to implement user-defined report templates and instant access to the stored data through digital archiving make it a flexible tool for image analysis and storage of different imaging modalities data including B-mode, M-mode, Pulsed (PW) Doppler mode, Continuous (CW) wave Doppler mode, Power Amplitude Doppler mode, Color Doppler mode, Doppler Tissue Imaging and 3D/4D imaging modes.

**Intended Use**

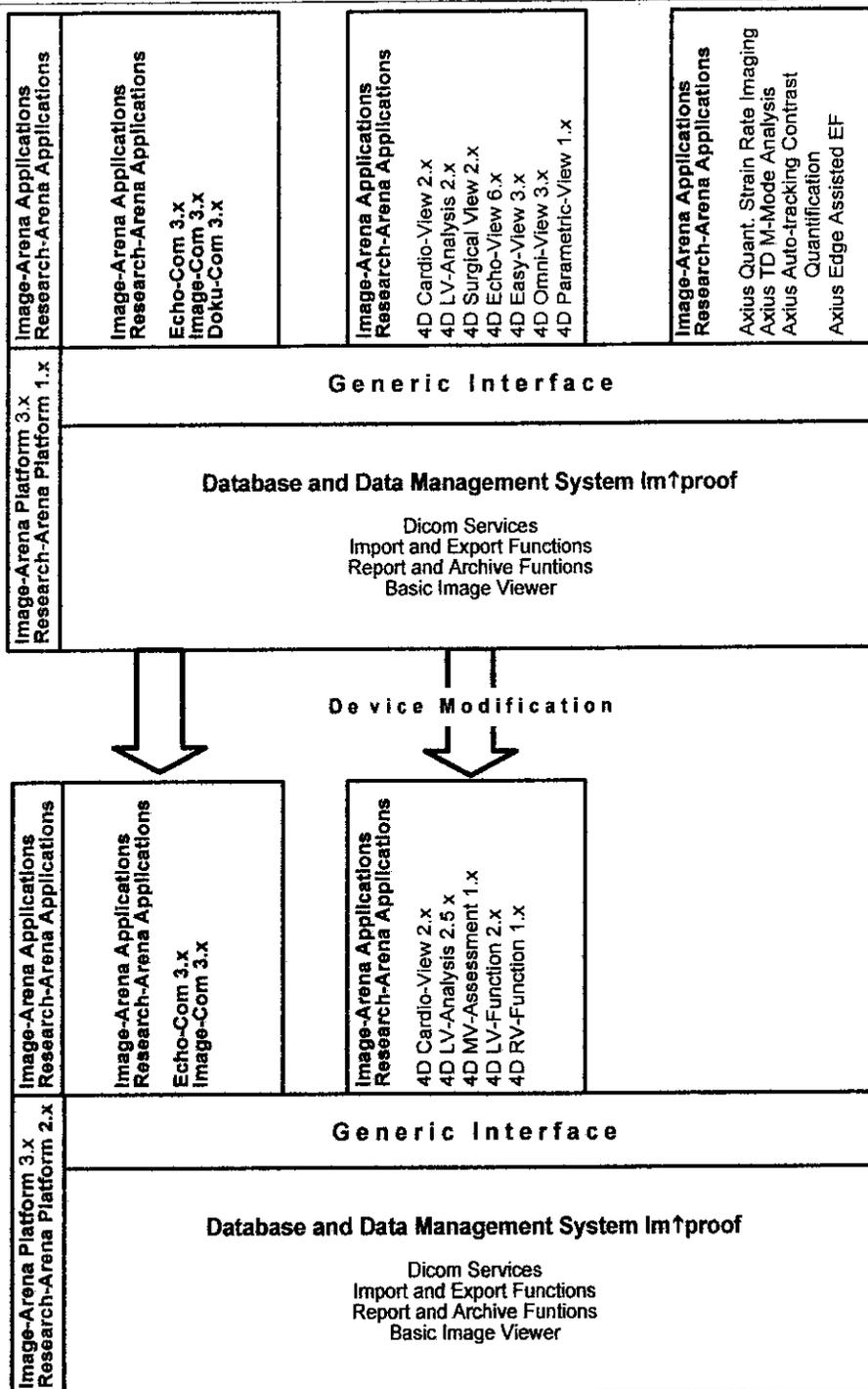
The Image-Arena/Research-Arena Applications software tool package is intended to retrieve, store, analyze and report digital ultrasound studies. The Image-Arena Platform and the Research-Arena Platform are based on a SQL – database intended as image management system especially for medical ultrasound studies. The Image-Arena/Research-Arena Applications software can import certain digital 2D or 3D image file formats for 2D/3D and 4D tomographic reconstructions and surface rendering.

The software is suited to stand-alone workstations as well as networked multi-system installations and is therefore an image management system for research and routine use in both physician practices and hospitals. It is intended as a general purpose digital medical image processing tool for cardiology, radiology, neurology, gastroenterology, urology, surgery, obstetrics and gynecology.

**Technological Characteristics Comparison**

The Image-Arena/Research-Arena Applications software tool package is modular structured and consists of different software modules, combining the advantages of the previously FDA cleared software product:

K040546      Image-Arena Applications      Research-Arena Applications



**Predicate Devices**

Image-Arena Applications  
 Research-Arena Applications  
 on  
 Image-Arena Platform 3.x  
 Research-Arena Platform 1.x  
 K 040546

**New Device**

Image-Arena Applications  
 Research-Arena Applications  
 on  
 Image-Arena Platform 3.x  
 Research-Arena Platform 2.x



**Discussion according non-clinical performance data testing**

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

**Discussion according clinical performance data testing**

The overall product concept was clinically accepted and the clinical test results support the conclusion that the device is as safe as effective, and performs as well as or better than the predicate device.

**Test Conclusions of non-clinical and clinical performance data**

Test results support the conclusion, that the device is as safe as effective, and performs as well as or better than the predicate device.

Munich, Jan. 29<sup>st</sup>, 2007



**Inge Scheidt**  
QM & RA Manager



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Ms. Inge Scheidt  
QM & RA Manager  
TomTec Imaging Systems GmbH  
Edisonstrasse 6  
Unterschleissheim, Bavaria D-85716  
GERMANY

**JUN 20 2007**

Re: K071232  
Trade/Device Name: Image-Arena Platform 3.0; Research-Arena Platform 2.0;  
Echo-Com 3.x; Image-Com 3.x; 4D Cardio-View 2.x;  
4D LV-Analysis 2.5x; 4D RV-Function 1.x;  
4D MV-Assessment 1.x; and, 4D LV-Function 2.x  
Regulation Number: 21 CFR §892.2050  
Regulation Name: Picture archiving and communications systems  
Regulatory Class: II  
Product Code: LLZ  
Dated: April 19, 2007  
Received: May 7, 2007

Dear Ms. Scheidt:

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.



*Protecting and Promoting Public Health*

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.

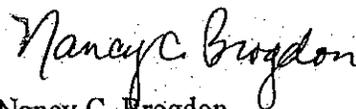
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
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): K091232

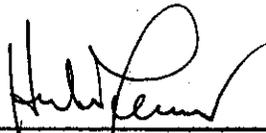
Device Name:

- Image-Arena Platform 3.0
- Research-Arena Platform 2.0
- Echo-Com 3.x
- Image-Com 3.x
- 4D Cardio-View 2.x
- 4D LV-Analysis 2.5 x
- 4D RV-Function 1.x
- 4D MV-Assessment 1.x
- 4D LV-Function 2.x

Indications for Use:

The Image-Arena and Research-Arena Platform Software is intended to serve as a data management platform for clinical application packages.

As the Image-Arena and Research-Arena Applications software tool package is modular structured, the clinical applications packages are indicated as software packages for analysis of the left ventricle in heart failure patients, to analyze pathologies related to the Mitral Valve and for analysis of the right ventricle in all patients with a need of right heart function diagnosis.



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K091232

Prescription Use   
(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)