K083348

TOMTEC
IMAGING SYSTEMS

Sep 30th, 2008

Traditional 510(k) Summary

DEC 23 2008

Image-Arena Platform 4.0 / Server Manager 4.0
Echo-Com 4.0
Image-Com 4.0

Owner's Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person

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

Common, Classification & Proprietary Names

Common Name:	Various Image Analysis System Software
Classification Name:	Picture archiving and communications system
Proprietary Name(s):	Image-Arena Applications

Image-Arena Platform 4.0 / Server Manager 4.0
Echo-Com 4.0
Image-Com 4.0

Predicate Device

TomTec	K071232	Image-Arena Applications Research-Arena Applications
Philips Medical Systems North America Co.	K061995	Xcelera

Device Description

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

It is suited as stand-alone workstations as well as networked multi-system installations. Image Arena is developed as a common interface platform for TomTec and 3rd party clinical application packages (CAPs) that can be connected to Image-Arena through the 3rd party Interface. The different application packages have all access to the central database and can be enabled on a modular basis thus allowing custom tailored solutions of Image-Arena.

The Image-Arena Application is a software tool package designed for analysis, documentation and archiving of ultrasound studies in multiple dimensions and X-ray angiography studies.

The Image-Arena Application 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 (K071232) and Xcelera (K061995).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 Image-Arena Application offers 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) 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 2D, 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 software tool package is intended to retrieve, store, analyze and report digital ultrasound and XA studies. The Image-Arena platform is based on a SQL – database and is intended as an image management system for images of the modalities US and XA.

The Image-Arena software can import certain digital 2D or 3D image file formats of the modalities US and XA.

The software is suited for stand-alone workstations as well as for networked multi-system installations and therefore is 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.

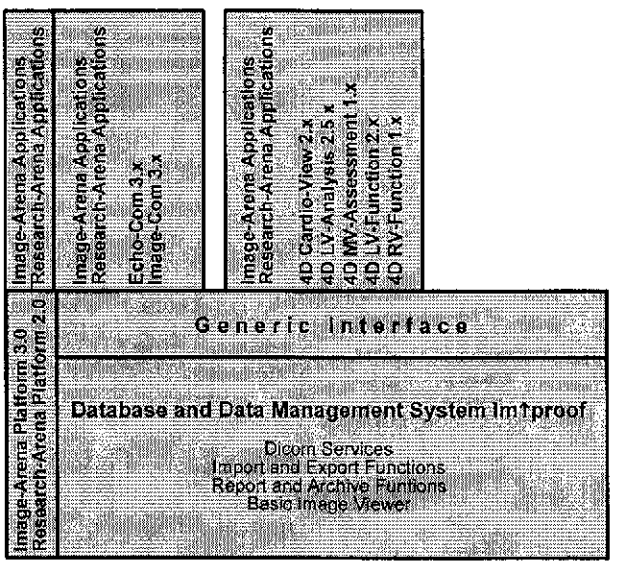
Technological Characteristics Comparison

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

K071232 Image-Arena Applications Research-Arena Applications
K061995 Xcelera, Philips Medical Systems, North America Co.

Predicate Devices:

TomTec Image-Arena and Research-Arena Applications



Predicate Devices:

K071232

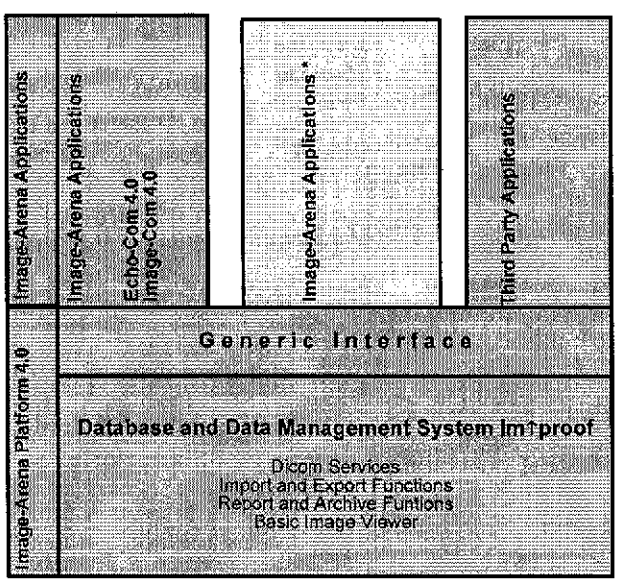
TomTec Image-Arena and Research-Arena Applications

K061995

Xcelera

New Device:

TomTec Image-Arena Applications



* IA 3.0 applications

New Device:

TomTec Image-Arena Applications

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, Sep 30th, 2008

J. Scheidt

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Ms. Inge Scheidt
TomTec Imaging Systems, GmbH
Edisonstrasse 6
D-85716 Unterschleissheim
GERMANY

Re: K083348
Trade/Device Name: Image-Arena Applications (Image-Arena Platform 4.0 / Server Manager 4.0/ Echo-Com 4.0/ Image-Com 4.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 30, 2008
Received: November 13, 2008

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 (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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting 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): K083348

Device Name:

Image-Arena Applications
Image-Arena Platform 4.0 / Server Manager 4.0
Echo-Com 4.0
Image-Com 4.0

Indications for Use:

The Image-Arena Platform Software is intended to serve as a data management platform for clinical application packages. It provides information that is used for clinical diagnosis purposes.

The software is suited for stand-alone workstations as well as for networked multi-system installations and therefore is 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.

As the Image-Arena Applications software tool package is modular structured, clinical applications packages with different indications for use can be connected.

Echo-Com software is intended to serve as a versatile solution for Stress Echo examinations in patients who may not be receiving enough blood or oxygen because of blocked arteries

Image-Com software is intended for reviewing, measuring and reporting of DICOM data of the cardiac modalities US and XA. It can be driven by Image-Arena or other third party platforms and is intended to launch other clinical applications.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083348