K110595

TOMTEC IMAGING SYSTEMS

APR - 7 2011

March 23rd, 2011

Traditional 510(k) Summary

4D Sono-Scan 1.0

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
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Common, Classification & Proprietary Names

Common Name: Various ultrasound Image Analysis System Software

Classification Name: Programmable diagnostic computer

Proprietary Name(s): **4D Sono-Scan 1.0**

Predicate Devices:

Predicate Device 1	K020561	Sono-Scan, Sono-Scan Pro, Cardio-Scan, TomTec Imaging Systems GmbH
Predicate Device 2	K071232	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, 4D Cardio-View 2.x component only, TT Imaging SystemsGmbH

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Device Description

The 4D Sono-Scan 1.0 is a clinical application package for high performance PC platforms based on Microsoft® Windows® operating system standards. 4D Sono-Scan 1.0 is proprietary software for the analysis, storage, retrieval, reconstruction and rendering of digitized ultrasound B-mode images.
The data can be acquired by ultrasound machines that are able to acquire and store 4D datasets (i.e. Toshiba Aplio XG or Zonare Z.ONE). The digital 3D/4D data can be used for basic measurements like areas, distances and volumes.

4D Sono-Scan 1.0 is compatible to different TomTec Image-Arena platforms and their derivatives (i.e. Zonare IQ Workstation) for offline analysis. The platform enhances the workflow by providing the database, import, export and other advanced high-level research functionalities. All analyzed data and images will be transferred to the platform for reporting and statistical quantification purposes via the Generic CAP Interface.

The Generic CAP (= clinical application packages) Interface is used to connect clinical application packages (=CAPs) to platforms to exchange digital medical data.

Intended Use

4D Sono-Scan 1.0 is intended to analyze digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.
The 4D Sono-Scan 1.0 reads certain digital 3D/4D image file formats for reprocessing to a proprietary 3D/4D image file format for subsequent 3D/4D tomographic reconstruction and rendering. It is intended as a general purpose digital 3D/4D ultrasound image processing tool.

Indications for use

4D Sono-Scan 1.0 intended as software for reviewing 3D/4D data sets and perform basic measurements in 3D.

Technological Characteristics Comparison

For detailed comparison of all software functionalities of the subject device and the predicate devices refer to Chapt.12: Substantial Equivalent discussion.

Discussion according non-clinical performance data testing

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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. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Discussion according clinical performance data testing

The overall product concept was clinically accepted and the clinical test results support the conclusion that the subject device is as safe as effective, and performs as well as the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the subject device is as safe as effective, and performs as well as or better than the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Munich, March 23rd, 2011

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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

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Re: K110595
Trade/Device Name: 4D Sono-Scan 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 31, 2011
Received: March 2, 2011

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110595

Device Name:

4D Sono-Scan 1.0

Indications for Use:

4D Sono-Scan 1.0 intended as software for reviewing 3D/4D data sets and perform basic measurements in 3D.

Prescription Use ___X___ (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)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110595