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K020561

TOMTEC
IMAGING SYSTEMS

December 21, 2001

Special 510(k) Summary

Sono-Scan
Sono-Scan Pro
Cardio-Scan

Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person

Florian Eisenberger
Director, Regulatory Affairs & Quality Assurance
Phone ++49-89-32175-830
fax ++49-89-32175-750

Common, Classification & Proprietary Names

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Proprietary Name:	Sono-Scan
	Sono-Scan Pro
	Cardio-Scan

Predicate Device

TomTec Echo-Scan K993394

Device Description

The TomTec acquisition software products Sono Scan and Cardio Scan are combining 3D and 4D Acquisition Software for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing. It is the appropriate Software solution for TomTec's add-on accessories for existing ultrasound imaging systems, and is intended to control position and movement of ultrasound transducers for the acquisition of 2 dimensional image slices throughout a volume of interest. The 4D Sono Scan™ Software acquires sets of 2D images and stores them digitally in a special 3D image file format for subsequent 3D tomographic reconstruction and surface rendering

The 4D Sono Scan™ is a software module for the high performance computer system Compact High or Professional based on Microsoft Windows 2000/XP™ operating system standards.

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Intended Use

Sono Scan/Cardio Scan™ is intended to acquire, store, retrieve and analyze digital ultrasound images and Color Doppler images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.
Sono Scan/Cardio Scan™ can import certain digital 2D or 3D image file formats for 3D tomographic reconstructions and surface rendering. It is intended as a general purpose image acquisition and digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastro-enterology, urology, surgery, obstetrics and gynecology.

Technological Characteristics Comparison

The new Sono Can/Cardio Scan is a modified version of the filed Echo-Scan system, which has been transferred to Windows 2000/XP operating system standards.
The graphic user interface has been improved for faster and easier application.
Sono Scan/Cardio Scan is a clinical application oriented subset of the Echo-Scan Software, which makes handling easier and more efficient.

Test Discussion

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.

Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications.

December 21, 2001 Florian Eisenberger

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

Mr. Florian Eisenberger
Manager, Regulatory Affairs
TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim
Bavaria, GERMANY

Re: K020561
Trade/Device Name: TomTec Sono-Scan, Sono-Scan Pro, Cardio-Scan
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: April 8, 2002
Received: April 16, 2002

Dear Mr. Eisenberger:

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 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:

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" (21 CFR Part 807.97). 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

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

Enclosure

510(k) Number (if known):_____

Device Name:_ TOMTEC Sono-Scan, Sono-Scan Pro, Cardio-Scan

Indications For Use

Sono-Scan/Cardio-Scan™ is intended to acquire, store, retrieve and analyze digital ultrasound images and Color Doppler images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.
Sono-Scan/Cardio-Scan™ can import certain digital 2D or 3D image file formats for 3D tomographic reconstructions and surface rendering. It is intended as a general purpose image acquisition and digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastro-enterology, urology, surgery, obstetrics and gynecology.

(PLEASE DO NOT WRITE BELOW LINE LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020561

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)