K993398

NOV - 5 1999

TOMTEC
IMAGING SYSTEMS

August 30, 1999

Special 510(k) Summary
EchoView 4.x

Name and Address
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Contact Person
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Common, Classification & Proprietary Names

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Proprietary Name:	Echo-View
	Easy-View
	Omni-View

Predicate Device

TomTec Echo-View K934139

Device Description

The Echo-Viewis a software module for high performance computer systems based on Microsoft Windows NT™ 4.0 operating system standards. Echo-Viewis proprietary software for the analysis, storage, retrieval and reconstruction of digitized ultrasound B-mode images and Color Doppler images.
The data can be acquired by a TomTec acquisition station or by a 3D capable ultrasound system. The result of acquired images allows a 3-dimensional volume to be reconstructed by Echo-View. The digital 3D / 4D data set can be used for 2D and 3D measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1999

Florian Eisenberger
Manager Regulatory Affairs
TomTec Imaging Systems
Edisonstrasse 6
857176 Unterschleissheim,
Germany

Re: K993398
Echo-View 4.x, Easy-View 1.x, Omni-View 1.x
Dated: September 30, 1999
Received: October 8, 1999
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Eisenberger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993398

Device Name: TOMTEC Echo View

Indications For Use

Echo-View™ 4.X is intended to retrieve, analyze and store digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing. Echo-View™ 4.x can import certain digital 2D or 3D image file formats for 3D tomographic reconstructions and surface rendering. It is intended as a general purpose digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastroenterology, 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)

David A. Krym

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993398

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