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510(k) Summary TomTec Echo-Scan with Freehand Scanning

Name and Address

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Common, Classification & Proprietary Names

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| Common Name: | Digital Ultrasound Image Analysis System |
| Classification Name: | Ultrasonic Pulsed Echo Imaging System |
| Proprietary Name: | TomTec Echo-Scan |

Predicate Device

TomTec Echo-Scan K941322, dated July 27, 1995

Device Description

The TomTec Echo-Scan is a high performance computer system based on Intel motherboard and Microsoft DOS/Windows standards. It incorporates a proprietary image digitizer circuit board and proprietary software for the acquisition, analysis, storage and retrieval of digital 3D ultrasound image data sets. The TomTec Freehand Scanning Device records ultrasound transducer spatial position in six degrees of freedom during use. 2D ultrasound images are acquired sequentially in a series of steps as the ultrasound transducer is swept across the patient scan site.



TomTec Imaging Systems, Inc.

Intended Use

The TomTec Echo-Scan is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing. It is an add-on accessory for existing ultrasound imaging systems, and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. The Echo-Scan acquires sets of 2D images and stores them digitally in the TomTec standard 3D image file format for subsequent 3D tomographic reconstruction and surface rendering with either the Echo-Scan or Echo-View. It is intended as a general purpose digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastroenterology, urology, surgery, obstetrics and gynecology. The TomTec Freehand Scanning Device is intended for acquiring a sequence of conventional 2D ultrasound images with transducer position recorded for each image acquired. The resulting image data set is intended for storage in the TomTec standard 3D image file format for subsequent 3D tomographic image reconstruction.

Technological Characteristics Comparison

The Echo-Scan system has been modified to add freehand scanning. This change expands the selection of image acquisition accessory devices (or probe carriage devices) available to control and/or monitor ultrasound transducer movement during image acquisition. With freehand scanning, the user scans a patient with the transducer held in the hand as he customarily would. This is made possible by using a coordinate tracking system. The coordinate tracking system provides spatial coordinates which can be encoded for each 2D image acquired as the transducer is moved.

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.