K960602

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510(k) Summary

Date:	26 February 1996
Submitter:	Toshiba America Medical Systems, Inc. 2441 Michelle Drive P.O. Box 2068 Tustin, CA 92681-2068
Contact:	Steven M. Kay (714) 730-5000
Classification Name:	Ultrasonic Pulsed Echo Imaging System Modification
Classification:	Class II per 21 CFR 892.1560
Device Tier:	2, according to the December 15, 1993 DRAERD Triage Pilot Program
Common Name:	Amplitude Doppler
Proprietary Name:	Color Angio
Model Name:	Color Angio for the SSA-340A Diagnostic Ultrasound System

Establishment Registration Number: 2020563

Compliance With Performance Standards:

This device complies with the Performance Standards for Electronic Products, 21 CFR 1010, as administered by the Center for Devices and Radiological Health and with CDRH guidances "Revised 510(k) Diagnostic Ultrasound Guidance for 1993", "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices"and "Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment". It also complies with the Japanese (JIS) and European (IEC-601-1) voluntary standards and the ISO-9001 manufacturing standard.

Substantial Equivalence Summary:

Color Angio is a post-processing modification to the Power Mode display that was cleared with the SSA-340A system in K941352. It is an amplitude based color display subset of color doppler imaging that performs frame addition to accentuate minute vascular structures and signal the presence of blood, rather than the motion of flow. This feature is independent of velocity, angle of incidence and direction of interrogation and reduces the effects of aliasing. It does not change the acoustic output or doppler sensitivity characteristics of the SSA-340A system.