

Appendix X

K941593

## 510(k) Summary

MAY 17 1996

**Date:** 31 March 1994  
**Submitter:** Toshiba America Medical Systems, Inc.  
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**Classification Name:** Diagnostic Ultrasonic Transducer  
**Classification:** Class II per 21 CFR 892.1570  
**Device Tier:** 2, per the December 15, 1993 DRAERD Triage Pilot Program  
**Common Name:** Transcranial Doppler Transducer  
**Proprietary Name:** PSH-25GT  
**Model Name:** PSH-25GT  
**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" and "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices". It also complies with the Japanese (JIS) and European (IEC-601-1) voluntary standards and the ISO-9001 manufacturing standard.

### Substantial Equivalence Summary:

The PSH-25GT is to be used with the Toshiba SSH-140A Track I Diagnostic Ultrasound system and claims substantial equivalency to the PSF-37FT, which was cleared for use with the SSH-140A Diagnostic Ultrasound System via K894632 and with the P3-2 Transcranial Doppler transducer distributed by Advanced Technology Labs (ATL).

The PSH-25GT and PSF-37FT probes are manufactured by Toshiba Corporation of Japan and distributed by TAMS, have the same methods of manufacture, follow the same software verification and validation procedures and employ the same general technology. While the PSH-25GT and PSF-37FT mainly differ in their indications for use (transcranial doppler vs cardiac, respectively), the PSH-25GT and P3-2 probes are intended for transcranial doppler applications.

### Summary of Safety and Effectiveness

The PSH-25GT, when used with the SSH-140A diagnostic ultrasound system, utilizes high frequency sound waves, beyond the range of human hearing, to perform diagnostic examinations. These sound waves are a form of non-ionizing radiation which can be used to demonstrate anatomical structures. Ultrasonic waves are easily focussed for the examination of small quantities of material and short time span phenomena. Additionally, ultrasound is especially beneficial in the examination of soft tissues. Doppler imaging permits investigation of vascular flow via the use of non-ionizing energy, rather than requiring the employment of ionizing radiation. Use of non-ionizing doppler radiation makes the PSH-25GT/SSH-140A combination highly applicable for visualizing cephalic structures. The application of ALARA (as low as reasonably achievable) principles minimize any potential harmful effects. At diagnostic levels, the benefits of using ultrasound for imaging procedures far outweigh its risks.

#### The PSH-140A

1. labelling clearly specifies "Caution: Federal law restricts this device to use by or on the order of a physician";
2. is intended for a specific application which is familiar to medical practice and is substantially equivalent to devices legally entered into commercial distribution;
3. when used with the SSH-140A, employs software safety features to prevent acoustic intensities from exceeding Pre-enactment guidelines;
4. probe/ultrasound generator system electrical safety is assured through proper grounding and, where local codes require, is certified through electrical certification performed by a nationally recognized testing agent (NRTL);
5. the probe operation manual informs the user to practice the principles of ALARA;
6. thermal and mechanical safety aspects comply with the IEC-601-1 standard;
7. cleaning and disinfection protocols are detailed in the transducer operations manuals. Agents for cleaning and disinfection are readily available through common suppliers and labeling cautions the user to follow the agent's manufacturer's instructions.