K970047

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510(k) Summary

Submitter's Name: Toshiba America Medical Systems, Inc.
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Establishment Registration Number: 2020563

Device Proprietary Name: Phased Array Transducer - - PSK-20CT
Common Name: Diagnostic Ultrasound Transducer
[Fed. Reg. No.: 892.1570, Pro. Code: 90-ITX]

Regulatory Class: II
514 Performance Standards: None
Special Controls: None
Prescription Status: Prescription Device

Reason for Submission:
Modification of the SSA-380A

Substantial Equivalence Summary:
The PSK-20CT phased array transducer will add adult transcranial indications for use to the SSA-380A diagnostic ultrasound system. The addition of the PSK-20CT transducer follows the same software verification and validation procedures and employs the same general technology as that previously cleared for the SSA-380A system and transducers in K933743. The SSA-380A system software and hardware is only upgraded to recognize the addition of the PSK-20CT. Cleared patient contact materials and acoustic output intensities are unchanged. No other system changes were required. The PSK-20CT transducer is similar to the PSH-25GT transducer that was cleared for transcranial use with the SSA-270A and SSH-140A diagnostic ultrasound systems in K941593.

Based on a review of TAMS Complaint and MDR files for similar transducers, any potential failure of this transducer is not expected to result in an injury to the patient.