Summary of Safety & Effectiveness K964746

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Product Identification:

Name: HiSpeed CT/i with Performix Tube and Warp Scan Option

Submitting Correspondant: Larry Kroger - Regulatory Program Managers

Manufacturer: General Electric Medical Systems
16800 W. Ryerson Road
New Berlin, WI 53151

Distributor: Same as Manufacturer

Indications for Use:

HiSpeed CT/i with Performix Tube and Warp Scan Option is intended to provide 0.8 second 360-degree helical or axial scans as well as increase the maximum tube heat capacity and provides additional mA settings over our existing system.

Device Description:

The option is a software control key for the HiSpeed system that increases the allowable speed (Warp Scan), for single rotation to 0.8 seconds for axial and helical scanning as well as 0.5 second rotation for partial scan. The Performix tube provides an additional tube option for use on the HiSpeed Gantry. It is a metal cased tube that has a heat capacity of 6.3MHU. For HiSpeed CT/i systems the maximum available power increases. The new tube takes advantage of power capabilities of the power distribution unit that is currently provided with the system. The increase in available power will not require a change in hardware.

Materials: Materials and construction are equivalent to the HiSpeed CT/i and are compliant with UL 187, IEC 601-1, and 21 CFR Subchapter J

Design: The design of HiSpeed CT/i with Performix Tube and Warp Scan Option differs from the information covered in K940606 (HiSpeed CT/i) by the addition of the Performix tube which allows for the widening of mA specifications as well as the increased scan speed. Tube mounting has been strengthened with the new tube to allow for faster scanning.

Energy Source and Exposure Levels: Maximum available output power varies according to the power distribution unit on existing system (there are two possible PDUs in the installed base). 48 kw allows an mA range of 40 to 400 mA and 53 kW allows mA range from 10 to 440 mA. The Performix tube has a heat capacity of 6.3 million heat units (MHU). All else within the system remains the same as the HiSpeed CT/i K940606.

Principals of Operation: Same as HiSpeed CT/i K940606.

Features: The features with this option differ from HiSpeed CT/i K940606 only by the additional range of mA available (10 to 440mA) as well as the faster scan speed, 0.8 sec for full scan rotation axials and helicals instead of 1 sec. Partial scan of 0.5 seconds instead of 0.6 sec.

Accessories: No new accessories with this option, all accessories used are the same as HiSpeed CT/i.

Marketing History:

The HiSpeed CT/i with Performix Tube and Warp Scan Option is substantially equivalent to the currently marketed HiSpeed CT/i (K940606).

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are controlled by compliance with industry standards (UL 187 and IEC 601-1), the Federal performance standard (21 CFR Subchapter J), and appropriate directions and warnings in the labeling.

Conclusions:

The HiSpeed CT/i with Performix Tube and Warp Scan Option adds a tube option and increased speed options that intend to improve the speed and efficiency of CT exams. It is the same basic design as HiSpeed CT/i differing only in the tube used which allows for a broader range of mA selections. All other HiSpeed CT/i features are as submitted in K940606. The HiSpeed CT/i with Performix Tube and Warp Scan Option has no differences with regard to safety or effectiveness from HiSpeed CT/i.