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GE Medical Systems

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K970606

Summary of Safety & Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

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Product Identification
Name: CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options

Manufacturer: GE-YMS
7-127 Asahigaoka 4-Chome
Hino-Shi, Tokyo, Japan 191

Distributor: GE Medical Systems
3000 Grandview
Waukesha, Wi 53188

Marketed Devices:

The CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options is of comparable type and substantially equivalent to currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and have the same intended uses.

Device Description:

The ProSpeed Family of Systems are x-ray computed tomography scanners based on the ProSpeed Plus platform consisting of a gantry, patient table, console, computer and associated accessories.

Materials: Materials and construction are equivalent to the CT ProSpeed Plus and are compliant with UL 187, IEC 601-1, and 21 CFR Subchapter J.

Design: The design is essentially the same as the CT ProSpeed with HiLight detector (K944013) the difference being that the Fluoro Scan option includes an in-room monitor and a control pedestal. The control pedestal allows for gantry tilt and table positioning as well as initiation and termination of scanning.

Energy Source and Exposure Levels: The energy source and exposure levels are the same as those previously submitted for ProSpeed with HiLight Detector.

Principals of Operation: The same as ProSpeed with HiLight Detector.

Indications for Use:

The CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options is indicated for head and whole body x-ray computed tomography applications. These options are modifications which can be added to the existing family of ProSpeed Systems. The options include Warp Scan Option which is intended to provide 0.8 second 360-degree helical or axial scans.

Fluoro Scan Option is an almost "real time" reconstruction (Smart Recon) with a display latency of 0.8 to 1.6 seconds. An in-room monitor provides an image display with either a 3 frame/sec or 6 frame/sec display of 90 one second rotation scans. Controls are provided for the control of the table and gantry by a physician or their assistant during procedures that require imaging.

SmartPrep Option is a tool to aid in triggering a helical or axial series of scans after contrast is injected. It allows the operator to monitor contrast as it enhances. A series of images, acquired immediately after injection, is automatically displayed along with pre-selected regions of interest. A graph plots the increase in CT numbers. When the region of interest begins approaching peak enhancement the operator can see that happen on the graph and initiate the CT series.

Comparison with Predicate:

It is the opinion of GE Medical Systems that the CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options is of a comparable type and substantially equivalent to currently marketed head and whole body x-ray computed tomography systems with respect to design, material composition, energy source, and radiation characteristics.

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a hazard analysis and controlled by:

- Fault Tree Analysis to demonstrate the non-existence or extremely low probability of unwanted events.
- System evaluation to insure performance to specifications and Federal Regulations.
- Adherence to Industry and International Standards. (UL and IEC)

Conclusions:

Use of the CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options does not result in any new potential safety risks and performs as well as or better than devices currently on the market.