510(k) Premarket Notification
Number K944131

SUMMARY

K964890

(1) Submitted by:

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November 27, 1996

MAR - 6 1997

(2) Device Name: Anatom 2000, HA+ or A+ Model; current product (A models) are distributed by Philips Medical systems under the model names (Tomoscan M / EG). This product will also be sold by Philips. This system is the same as the current system, but with the additional capabilities or options of performing MPR and Helical Scanning. The system is classified as a Computed Tomography X-ray System, Product Code: JAK.

(3) Predicate Device: Analogic Corporation - Anatom 2000,(A) model; Philips Medical systems - (Tomoscan M / EG); K944131 (SE) 1/25/95.

(4) Device Description: The Anatom 2000 consists of a light weight gantry with built-in computer and power supplies, patient table, and operating console with display. The gantry uses a translatable rotating disk with X-ray generator and tube, pre-collimator, 384-element solid state detector array, control computer, energy storage banks, communications link, data acquisition, and power management and power supply electronics. The gantry is driven by a brushless DC motor. The gantry can be tilted +30/-25 degrees from the vertical and can translate horizontally approximately ±7" (±178mm) for a total travel distance of approximately 14 inches (356mm). The high precision, highly stabilized X-ray generator is powered by sealed dry batteries which essentially eliminate dependence on AC line quality. The battery banks are charged in the stand-by mode from the main power source. Even when charging, the total line power is less than 1500 watts. The patient table connected to the gantry is driven by brushless DC motors for horizontal and vertical movement under microprocessor control. In the event of a power failure, the table top can be manually removed from the gantry opening so that the patient can be conveniently removed from the system.

The operator console or work station consists of a Sun Sparc 5 computer and keyboard, 17" monitor, audio system, emergency controls, and uninterruptible power supply. The work station is responsible for the control-selection of the gantry, table, image processor, X-ray generator and tube.

(5) Intended Use: The Anatom 2000 is a whole body CT scanning system. It is intended to be used as a Computed Tomography X-ray System for diagnostic purposes, producing cross-sectional images of the body through computer reconstruction of X-ray transmission data from the same axial plane taken at different angles. This type of system has been classified as a Class II device under 21 CFR 892.1750.

(6) In the opinion of Analogic Corporation, the Anatom 2000 Computed Tomographic X-ray System with the 2 additional options (HA+ / A+ model) is of comparable type in design, shape, materials, functionality and technology, and is substantially equivalent to the above indicated predicate device previously cleared through the 510(k) process under K944131.