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K962738

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) sammary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87 (h).

Identification Of Submitter

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Identification Of The Product

Device Proprietary Name: Millennium MT and Millennium MG Nuclear Medicine Systems.
Common Name: Nuclear Medicine Scanner.
Classification Name: Emission Computed Tomography System, 21 CFR 892.1200.

Establishment Reg. Number: 2126677
Manufacturing Location: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices

Predicate Devices:

System	Manufacturer	510(k) #
Optima Nuclear Medicine System	GE Medical Systems	K915470
Phoenix Nuclear Medicine System	GE Medical Systems	K951144
Maxxus Nuclear Medicine System	GE Medical Systems	K924498
Vertex Nuclear Medicine System	ADAC	K922080

Device Description

Millennium MT Nuclear Medicine System will be used for general purpose applications - planar, whole body and SPECT (Single Photon Emission Computed Tomography). It will support two Digital CSE (correlated signal enhancement) rectangular detectors in 180 degree (opposed) geometry (DH position). Whole body studies will be accomplished through the gantry ring. The gantry/detector assembly will support step-and-shoot

tomography, continuous tomography, elliptical tomography, simultaneous anterior/ posterior whole body and whole body contour applications. Prone/supine/sitting/sideways patient studies will be accommodated by the gantry/detector assembly.

In addition to the Millennium MT capabilities, the Millenneum MG provides a 101.25 degree cardiac detector angulation (VG position) functionality implemented through the addition of a locking motor, additional software to automate the positioning and set up protocols.

The MT system can be upgraded to a MG system by adding a locking motor to the gantry and removing software locks to enable all of the MG software functionality

Indications For Use

The Millennium MT and MG systems are designed to acquire data for whole body and multi-slice images. The Millennium MT and MG are intended for use as diagnostic imaging devices. When used with appropriate pharmaceuticals, they produce images representative of the internal distribution of radioactivity in head or body. These systems allow you to acquire data for high resolution three dimensional, static gated or dynamic images of biochemical and metabolic processes.

Comparison With Predicate Device

The Millennium MT/MG, and predicate devices are nuclear imaging systems which acquire information from radio-labeled pharmaceuticals and display images. A comparison of the features indicates that the Millennium MT/MG have the same intended use as the predicate devices. No new safety or effectiveness concerns are raised by the design of the Millennium MT/MG. It shares common hardware with the Phoenix system.

Summary Of Studies

Initial information indicates that the Millennium systems will conduct planar, whole body, SPECT, tomographic and cardiac imaging. Cardiac studies can be accomplished through use of variable geometry detectors (MG model), which can be positioned at the 101.25 degrees to one another.

Conclusions

In the opinion of GE Medical Systems, the Millennium MT/MG are substantially equivalent to the Optima, Phoenix and Maxxus Nuclear Medicine Systems manufactured by GE Medical Systems (510(k) #'s K915470 and K951144 and K924498 respectively), and the ADAC Vertex (510(k) # K922080). The Millennium MT/MG have the same intended use as the predicate devices. No new safety or effectiveness concerns are raised by the design of the Millennium MT/MG.