

UGM Medical Systems Inc.

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K973396

510(k) SUMMARY

- 1) Submitter: UGM Medical Systems
3611 Market Street
Philadelphia, PA 19104
Contact person: Gerd Muehlelehner
Date of Summary: September 25, 1997
- 2) Name of device: Quest 300H
Common name: Positron emission tomograph
Classification name: Emission Computed Tomography System
- 3) Equivalence: PENN-PET Scanner
Manufacturer: UGM Medical Systems
510(k) Number: K930428

JAN 21 1998

FDA/CDRH/ODE/DNC

SEP 29 12 34 PM '97

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4) Description of Device:

The Quest Positron Emission Tomography (PET) system is a whole body scanner designed to provide true volumetric imaging. Quest is intended for use as a diagnostic imaging device. When used with appropriate radiopharmaceuticals, it produces images representative of the internal distribution of radioactivity in the head or the body.

The system allows you to reconstruct high-resolution three-dimensional, static, gated or dynamic images of biochemical and metabolic processes and then enables you to display, process and analyze these images according to your specific needs.

PET is based on the fact that certain radionuclides decay by positron emission. The positron annihilation results in the emission of two 511 keV gamma-rays which are emitted in opposite directions. Coincidence detection of both gamma rays localizes the decay along a line. By using 6 large position-sensitive detectors around the patient, counts along many parallel lines and at many angles are acquired simultaneously. By using reconstruction algorithms, the internal distribution of radioactivity can be determined.

The scanner provides a 25 cm axial field of view for whole-organ coverage, as well as a 50 cm transverse scan field of view for body studies.

The Quest uses 6 rectangular NaI(Tl) scintillation crystals, each of which is coupled to 48 photomultipliers (PMTs). 42 of the (PMTs) are 2.5 inch diameter round arranged in a close packed hexagonal pattern, and the remaining six are half-hex (PMTs) positioned at the edges to fill out the rectangular crystal area. The detector separation is 85 cm.

5) Intended Use:

Quest is intended for use as a diagnostic imaging device. When used with appropriate radiopharmaceuticals, it produces images representative of the internal distribution of radioactivity in the head or the body.

6) Comparison to predicate device:

The Quest 300H has been improved and this application represents a submission of the changes relative to the version of the Quest 300H which has been previously approved.

The following is a list of modifications.

a) **Improved patient safety.** Since the original submission in 1993, we have obtained compliance to the UL standard, the European IEC standard and, when we ship to Europe, obtain CE certification. This has raised the level of patient safety through a variety of small changes.

b) **Improved patient data documentation.** All programs which display patient images now show the patient's name, the filename, and date of image acquisition. This reduces the risk of misidentification of filmed or printed images.

c) **Improved User's Manual.** The manual has been expanded significantly and now contains chapters describing the equipment in an overview, contains a chapter on safety, and shows examples of the display on the screen.

d) **Whole-body scanning.** A whole body scanning mode has been implemented in which the patient is moved axially into or out of the scanner after each frame of data collection. The user is prompted to perform the motion and must depress a button during motion for safety. The images are reconstructed into a single data set which can be viewed as transverse, sagittal and/or coronal images.

e) **Additional reconstruction filters and methods.** Since 1993 we have improved the reconstruction program by adding several new filters and by including an iterative reconstruction algorithm (OSEM).

f) **Image registration & importation of CT/MRI images.** In order to help physicians correlate information from PET scans with CT and/or MRI scans, we can now import images from other medical imaging equipment using the DICOM standard. These images can then be displayed either next to or superimposed onto the PET images.

g) **Improved method of attenuation correction.** The present method of performing attenuation correction uses a Ge-68/Ga-68 source for measurement of the attenuation coefficients. By using Cs-137 instead of Ge-68/Ga-68 and detecting the single gamma-rays of Cs-137 (662 keV) instead of measuring the Ga-68 emissions in coincidence, we can acquire data at a higher data rate and therefore obtain better quality (i.e. statistically more accurate) images in a shorter time.

h) **Segmentation of transmission images.** The process of segmentation consists of identifying and differentiating between lung, tissue and background. Since the attenuation values in the transmission images are significantly different between these three compartments, the software can identify them and then assign a constant value to each. This process reduces the statistical fluctuations significantly and further improves the attenuation corrected emission images.

i) **Curved detectors.** We plan to replace the flat detectors with curved detectors in order to improve the spatial resolution for brain imaging.

j) **Larger patient aperture.** At the present time the patient aperture is 50 cm, which eliminates only very few patients, but which means that approximately 5% of all patients

need to squeeze into the opening. By enlarging the patient aperture to 56 cm, we make it easier to introduce patients into the scanner.

k) Re-packaging of components. The printed circuit boards necessary to perform the data acquisition have been reduced in size and number to the point that all the electronics can now be packaged inside the scanner itself and does not require a separate electronics cabinet anymore.

l) Improved countrate performance. We have been able to improve the countrate performance by incorporating more processing power into the redesigned electronics. This has been achieved by using better timing discriminators, allowing us to detect coincidence events more accurately and by processing events occurring in different locations and in different detectors in parallel.

All the above changes are improvements to the existing PET scanner without altering its function.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1998

Gerd Muehlechner, Ph.D.
President
UGM Medical Systems, Inc.
3611 Market Street
Philadelphia, PA 19104

Re: K973396
Sentry PET Imaging System
Dated: December 5, 1997
Received: December 8, 1997
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Dr. Muehlechner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmmain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973396

Device Name: Quest

Indications For Use:

The Quest Positron Emission Tomography (PET) system is a whole body scanner designed to provide true volumetric imaging.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David G. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973396