

NOV 4 1998

K982855

**510(k) SUMMARY OF  
SAFETY AND EFFECTIVENESS DATA**

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information

- A. Submitted By: DIGIRAD Corporation  
9350 Trade Place  
San Diego, CA 92126
- Contact Person: R. Scott Huennekens  
Vice President of Administration &  
Regulatory Affairs
- B. Classification Name: Computed Emmission Tomography System  
Common/Usual Name: SPECT Gamma Camera System  
Trade Name: Digirad 2020tc SPECT Imaging System

C. Predicate Device:

<u>Sponsor</u>	<u>Product</u>	<u>510(k) No.</u>
SCINTICOR	SIM 400 System	K885054
SITCO Inc.	NuQuest Nuclear Medicine Computer	K953255

D. Device Description:

The Digirad SPECT Rotating Chair is an option to Digirad 2020tc Imager™ so that SPECT imaging with patients in the upright, seated position may be performed. The Digirad 2020tc Imager™ together with the SPECT Rotating Chair will be the Digirad 2020tc SPECT Imaging System.

The Digirad SPECT Rotating Chair assembly is mounted on a mobile platform and a fixture on which the gamma camera detector head of the 2020tc Imager is mounted. The detector head is connected by way of cables to the processing computer, which includes the associated recording and

permanently aligned with respect to the center-of-rotation of the chair assembly, faces towards the patient throughout the period of data acquisition, and accommodates various patient heights with the adjustment of the vertical position. The center of the imaging field-of-view remains fixed relative to the chair's center-of-rotation; however, the horizontal position of the detector head may be moved closer or farther from the surface of the body. The detector head position may be adjusted at any time during the rotation to ensure that the detector head remains as close as possible to the body, but does not collide with an irregular body contour such as the shoulder, breast, etc. The chair assembly provides for the forward-backward (x) and side-to-side (y) adjustment of the chair position to ensure that the body part or organ to be imaged will remain entirely within the field-of-view during SPECT acquisition.

Radionuclide count data are collected at approximately 3 or 6 degree intervals during chair rotation. Data acquisition occurs for approximately 10-20 seconds after the chair rotates to and stops at the next position. Positional steps are adjustable, but remain the same once rotation and data recording have begun. Tomographic cross-sectional slices of the body (e.g., heart) are derived from the serial recordings using standard SPECT reconstruction methods.

E. Intended Use:

The Digirad 2020tc SPECT Imaging System is intended for use in the generation of planar and Single Photon Emission Computed Tomography (SPECT) clinical images in Nuclear Medicine applications. In so doing, the system produces images depicting the anatomical distribution of radioisotopes within the human body for interpretation by authorized medical personnel.

F. Device Comparison

The 2020tc SPECT Imaging System and the predicate devices have the same intended uses and operating principles. In addition, the 2020tc SPECT Imaging System and the NuQuest Medicine Computer use the same software for obtaining images, while the 2020tc SPECT Imaging System and the SIM 400 System utilize a rotating chair to obtain images.

G. Test Summary

Chair stability and patient motion were clinically evaluated in healthy volunteer subjects. The subjects were assessed for the degree of movement during twenty minutes of chair rotation. Results showed that in no case was any significant movement of the chest noted during the twenty minute simulated acquisition with the rotating chair.

Clinical imaging was performed using the rotating chair for SPECT in fourteen patients. Tomographic image quality was judged to be excellent by the Nuclear Medicine physicians at the investigational center and to be at least equal to images obtained from a reference SPECT capable gamma scintillation camera.

Cardiac phantom imaging was used to test the accuracy of reconstruction and identification of simulated myocardial perfusion defects. Results showed that the quality of reconstructed tomographic images of a test phantom, obtained with the rotating chair in conjunction with the solid state 2020tc Imager™ and associated processor software, was at least equal to images obtained with a reference SPECT capable gamma camera.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Esther Saltz  
Regulatory Consultant for Digirad Corporation  
Digirad Corporation  
9350 Trade Place  
San Diego, CA 92126-6334

Re: K982855  
SPECT Imaging System  
Dated: August 4, 1998  
Received: August 6, 1998  
Regulatory class: II  
21 CFR 892.1200/Procode: 90 KPS

Dear Ms. Saltz:

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 requirements, 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/dsma/dsmamain.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

INDICATION FOR USE

510(k) Number (If known): K982855

Device Name: Digirad 2020tc SPECT Imaging System

Indications for Use:

The Digirad 2020tc SPECT Imaging System is intended for use in the generation of both planar and Single Photon Emission Computed Tomography (SPECT) clinical images in Nuclear Medicine applications. The Digirad SPECT Rotating Chair is used in conjunction with the Digirad 2020tc Imager™ to obtain SPECT images in patients who are seated in an upright position.

Specifically, the 2020tc Imager™ is intended to image the distribution of radionuclides in the body by means of a photon radiation detector. In so doing, the system produces images depicting the anatomical distribution of radioisotopes within the human body for interpretation by authorized medical personnel.

David A. Segman  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K982855

Prescription Use   
(P 21 CFR 801.109)