K070542

Appendix 2: 510(k) Summary

MAR 2 3 2007

A. Sponsor

Digirad Corporation
13950 Stowe Drive
Poway, California 92064
Contact Person: Joel Tuckey
Tel: (858) 726-1527
Fax: (858) 726-1700

B. Date Prepared: February 23, 2007

C. Device Name

Trade Name: Cardius 1 XPO, Cardius 2 XPO, Cardius 3 XPO, and 2020tc SPECT Imaging System

Classification Name: System, Emission Tomography

D. Description of Changes

The proposed change involves use of a newer release of Segami Corporation's Mirage processing software on Digirad SPECT imaging systems. Previously cleared and marketed models of Digirad gamma cameras have always included earlier cleared releases of Mirage processing software as noted in our previous 510(k) submissions. This change seeks approval to market Digirad gamma cameras with Segami Mirage release 5.5, cleared under 510(k) #K043441, January 13, 2005, and later updated to release 5.6 by Segami Corporation. This release of Mirage software operates under a Windows XP operating system, and will be referred to as "Mirage XP" in this submission and Digirad labeling material (user manual, literature, etc). Mirage XP (Digirad's marketing name) and Segami's Mirage 5.6 are the same software program.

Mirage XP is an automated processing and interpretation software package. This software will be available as standard software on the Digirad imaging systems and/or as a standalone software package on a workstation or a laptop. The enhancements to previous versions of software include automated processing, preference based selections, improved EF algorithm and segment scoring for quantification and interpretation.

E. Intended Use

The intended uses of the Cardius series and 2020tc cameras have not changed, and are summarized in the "Indications for Use" form included with this submission.

F. Cleared/Predicate Device

The proposed change is a modification to the following Digirad cleared devices:

(1) 2020tc SPECT Imaging System and the SPECTour Chair (SPECT Imaging System), cleared on November 9, 1998 under 510(k) #K982855; and

(2) Cardius-1 and Cardius-2 SPECT Imaging System cleared on February 5, 2003 under 510(k) #K030085.

(3) Cardius-1, Cardius-2, Cardius-3, and 2020tc SPECT Imaging Systems cleared on July 13, 2005 under 510(k) #K051549

(4) Cardius-1, Cardius-2, Cardius-3, and 2020tc SPECT Imaging Systems cleared on October 4, 2005 under 510(k) #K052430

G. Conclusions Drawn from Testing

Testing was done confirming that the new Mirage XP software can be installed and functions as intended on Digirad imaging systems. Use of the Mirage XP software in conjunction with previously cleared acquisition software and OSEM reconstruction techniques results in no known anomalies in the devices that impact safety or effectiveness, including operator usage and human factors. The quality of the images produced with the Mirage XP software is equivalent to those seen in previous versions of Mirage software used on Digirad imaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Joel Tuckey
VP Quality
Digirad Corporation
13950 Stowe Drive
POWAY CA 92064-8803

MAR 2 3 2007

Re: K070542
Trade/Device Name: Cardius 1 XPO, Cardius 2 XPO, Cardius 3 XPO, and 2020tc SPECT Imaging Systems
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 23, 2007
Received: February 26, 2007

Dear Mr. Tuckey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use
510(k) Number (if known): ~~TBD~~ K070542
Device Name:
Cardius 1 XPO, Cardius 2 XPO, Cardius 3 XPO, and 2020tc SPECT Imaging Systems

Indications for Use:

Cardius 1 XPO, Cardius 2 XPO, Cardius 3 XPO Imaging Systems:

The Cardius product models are intended for use in the generation of cardiac studies, including planar and Single Photon Emission Computed Tomography (SPECT) studies, in nuclear medicine applications.

2020tc SPECT Imaging System:

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 R. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070542

Prescription Use ✓ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)