APPENDIX 1. 510(k) SUMMARY

A. Sponsor

FEB 0 5 2003

Digirad Corporation
9350 Trade Place
San Diego, California 92126-6334
Contact Person: Corey Stewart
Tel: (858) 537-2118
Fax: (858) 549-9789

B. Date Prepared: 1/06/03

C. Device Name

Trade Name: Cardius-1, Cardius-2

Classification Name: System, Emission Tomography

D. Device Description

The Cardius model cameras are gantry (open gantry, upright seated) devices designed for single- (Cardius-1) or dual-detector (Cardius-2) cardiac nuclear imaging studies. The device includes an acquisition/processing station, a gantry, one or two detectors, and a gantry-mounted patient imaging chair. The patient imaging chair is mechanized to accommodate patient loading and cardiac centering in the detector field of view.

The imaging chair motion control allows for acquisition of Cardiac SPECT and planar studies, including static, dynamic, gated/non-gated SPECT (circular orbit only).

E. Intended Use

The Cardius-1 and Cardius-2 are intended for use in the generation of cardiac studies, including planar and Single Photon Emission Computed Tomography (SPECT) studies, in nuclear medicine applications.

F. Predicate Device

The Cardius systems are substantially equivalent in design and intended use to the Digirad 2020tc SPECT Imaging System and the ADAC Forte (cardiac applications only).

G. Summary of Substantial Equivalence

The Cardius -1 and Cardius- 2 devices are substantially equivalent to the predicate devices in intended use, physical characteristics, performance specifications and safety characteristics.

H. Testing

Comprehensive verification and validation testing was performed with the Cardius-1 and Cardius-2 devices including; hardware, software, electrical safety, and clinical imaging All test results met pre-defined acceptance criteria. The quality of the clinical images produced were similar to the quality of the images produced by the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

Mr. Corey Stewart
Quality Assurance Manager
Digirad Corporation
9350 Trade Place
SAN DIEGO CA 92126-6334

Re: K030085
Trade/Device Name: Cardius-1 and Cardius-2
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: January 7, 2003
Received: January 9, 2003

Dear Mr. Stewart:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

APPENDIX 2. INDICATION FOR USE STATEMENT

510(k) Number (if known): K 030085

Device Name: Cardius-1, Cardius-2

Indications for Use: 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

David A. Clymer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030085