K082904

Appendix 2: 510(k) Summary

A. Sponsor

DEC 17 2008

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

B. Date Prepared: September 26, 2008

C. Device Name

Trade Name: STASYS™ Motion Correction Software
Common Name: Gamma Camera System
Classification Name: System, Emission Tomography
Product Code: KPS

D. Cleared/Predicate Devices

The STASYS™ Motion Correction Software is substantially equivalent to the following cleared devices:

(1) Cedars-Sinai Motion Correction (MoCo) Software cleared November 22, 2002 under K023110 for Digirad Corporation.

(2) Cedars-Sinai BPGS and MoCo software cleared April 27, 2001 under K010509 for GE/SMV America.

E. Device Description

STASYS™ is a software application developed by Digirad for the correction of SPECT acquisition motion artifacts from gated and non-gated projection datasets. When the program is activated, STASYS uses algorithms developed by Digirad to minimize motion error metrics over the set of acquired projections. The resulting STASYS corrected projections are presented to the operator for acceptance or rejection of the correction. With STASYS software, cardiac SPECT studies acquired with both parallel hole and non-parallel hole collimators, can be motion corrected. The STASYS software has the same indications for use and function as the Cedars-Sinai designed MoCo software, currently being used on Digirad SPECT imaging systems and processing workstations.

F. Intended Use

The indications for use are the same as the predicate devices. The STASYS Motion Correction Software program is intended for use in correcting patient motion artifacts in SPECT data acquired on a nuclear medicine gamma camera system.

G. Technology

In STASYS, Digirad internally developed proprietary algorithms are implemented using software technology. The externally developed algorithms used in the predicate devices are also implemented using software technology.

H. Testing

Verification and Validation tests were conducted to demonstrate the STASYS software module functioned as per its specifications. All tests passed with the actual results substantially matching the expected results. Testing included an evaluation of the software functionality and effectiveness as compared to the predicate devices, with results showing it performs as well.

I. Conclusion

Testing results demonstrate that the STASYS software meets the specifications and is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joel Tuckey
Vice President, Quality
Digirad Corporation
13950 Stowe Drive
POWAY CA 92064-8803

DEC 17 2008

Re: K082904
Trade/Device Name: STASYS™ Motion Correction Software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: September 26, 2008
Received: September 30, 2008

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 (PMA), 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting 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~~ K082904
Device Name:
STASYS™ Motion Correction Software

Indications for Use:

The STASYS Motion Correction software program is intended for use in correcting patient motion artifacts in SPECT data acquired on a nuclear medicine gamma camera system.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082904