K041218

MAY 2 4 2004

Inserted May 07, 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

A. Submitted By:

ADAC Laboratories
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Milpitas, CA 95035

Contact: Coleen Coleman
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B.

Device Trade Name:	Griffin SPECT/CT Imaging System
Common Name:	Single Photon Emission Computed Tomography Computed Tomography X-Ray
Classification Name:	System, Emission Computed Tomography, (892.1200) System, Computed Tomography X-Ray, (892.1750)
Device Class:	21CFR 892.1200, Class II 21 CFR 892.1750, Class II
Product Code:	90 KPS and 90 JAK

C. Date prepared: April 26, 2004

D. Predicate Device: Skylight Imaging System (K031705)
MX8000 IDT CT System (K012009)

E. Performance Standards

- 21 CFR 1020.30 – 1020.33 as applicable for Ionizing Radiation Emitting Products (Applicable Sections)
- NEMA NU-1

E. Intended Use:

Griffin is an imaging system combining the acquisition of single photon nuclear medicine images and images from an x-ray computed tomography system. Griffin may produce non-attenuation corrected and attenuation corrected images of the distribution of radiopharmaceuticals in the body as well as x-ray transmission images. The CT transmission data may be used to produce attenuation corrected nuclear medicine images. The nuclear medicine images and the CT images may be registered and displayed in a fused format (overlaid in the same orientation) to provide combined single photon and anatomical data for anatomical localization of the nuclear medicine data. Griffin may be used either as a separate single photon system, a separate CT system or as a combined CT and single photon system. The nuclear medicine and CT images may be transferred to other systems such as a radiation therapy planning system. The Griffin Imaging System should only be used by trained healthcare professionals.

F. Device Description:

The Griffin SPECT/CT Imaging System (Griffin) is a hybrid SPECT/CT system for performing CT studies, general nuclear medicine studies, or SPECT/CT sequentially (dual-modality studies) wherein the SPECT and CT studies may be automatically co-registered and displayed in fused form. Because the natures of the imaging modalities, they provide different information; the SPECT study yields functional information about metabolic processes and the CT study yields structural or anatomical information. As radionuclides become more tissue specific, diagnoses from nuclear images alone will be more difficult without the general anatomical detail less

specific agents provide. Thus fused SPECT and CT images will provide the information required for accurate and comprehensive diagnoses.

Griffin is constructed from two existing systems, the Skylight Imaging System (K031705) and the Brilliance CT (K012009). The Griffin has two acquisition consoles. One console is placed in the acquisition room itself, consistent with the SPECT convention, and the other console is placed in the shielded scanner control room, as required for CT. The acquisition stations provide a single user interface for both SPECT and CT patient acquisition set-up. The SKYlight and Brilliance system gantries remain intact as major subsystem components located within a common integrated housing. The combined Griffin SPECT-CT Imaging System is designed so that the system can operate in three modes: CT only, SPECT only, and combined SPECT/CT performed sequentially. No modifications have been made to either system, which would affect system performance.

Griffin is intended for use primarily as an imaging system combining the acquisition of single photon nuclear medicine images and images from an x-ray computed tomography system. The same clinical protocols and procedures are available on the Griffin Imaging System as in the predicate SPECT or CT systems. Acquired SPECT and CT images on the Griffin may be registered and displayed in a fused format (overlaid in the same orientation) to provide combined single photon and anatomical data to provide anatomical localization of the nuclear medicine image.

G. Comparison to Predicate Device:

The Griffin SPECT/CT Imaging System, like the predicate devices, SKYlight Imaging System and the Brilliance CT are similar in that all the devices consist of a full functional SPECT and CT system. The patient may have a diagnostic SPECT and CT scan performed consecutively without having to move the patient. The Griffin provides a mean to reach the diagnostic decision faster than the conventional way of imaging patients with both SPECT and CT systems in separate locations. The differences are overall system dimensions, room size requirements, and ease of use.

The combined Griffin SPECT-CT Imaging System is designed so that the system can operate in three modes: CT only, SPECT only, and combined SPECT/CT performed sequentially. The major difference is that the Griffin system has a common integrated housing for the major sub-system components. Griffin also provides a new dedicated SPET/CT table to allow the patient to be scanned on both systems in a single acquisition session. The common table also allows for parametric registration.

H. System Performance Test:

- Radiation safety by compliance and certification to the performance standards for ionizing radiation emitting product 21 CFR 1020.30 and 21 CFR 1020.3333. The radiation safety product report will be filed in accordance with 21 CFR 1002.10 with the Center for Device and Radiological Health.
- Electrical and mechanical safety is assured as the system is designed to applicable voluntary standards in the IEC 60601-1 series. The device performance was measured in accordance with the NEMA-NU-1 standard.

I. Conclusion:

The Griffin Imaging System is substantially equivalent to the predicate devices, the SKYlight Imaging System (K031705) and Brilliance CT (K012009) based upon similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2004

ADAC Laboratories
% Ms. Denise Leung Klinger
Principal Reviewer
Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K041218
Trade/Device Name: Griffin SPECT/CT Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: May 7, 2004
Received: May 10, 2004

Dear Ms. Klinger:

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 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

Inserted May 03, 2004

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K041218

DEVICE NAME: Griffin SPECT/CT Imaging System

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

Griffin is an imaging system combining the acquisition of single photon nuclear medicine images and images from an x-ray computed tomography system. Griffin may produce non-attenuation corrected and attenuation corrected images of the distribution of radiopharmaceuticals in the body as well as x-ray transmission images. The CT transmission data may be used to produce attenuation corrected nuclear medicine images. The nuclear medicine images and the CT images may be registered and displayed in a fused format (overlaid in the same orientation) to provide combined single photon and anatomical data for anatomical localization of the nuclear medicine data. Griffin may be used either as a separate single photon system, a separate CT system or as a combined CT and single photon system. The nuclear medicine and CT images may be transferred to other systems such as a radiation therapy planning system. The Griffin Imaging System should only be used by trained healthcare professionals.

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

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041218