510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

A. Submitted By:

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B.

Device Trade Name:	Precedence 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: May 6, 2005

D. Predicate Device:

Precedence SPECT/CT (cleared as Griffin) (K041218)
Predicate Philips Plus CT Scanner (K033326)
Brilliance CT, Private Practice CV configuration CT Scanner (K042293)

E. Performance Standards

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

F. Intended Use:

Precedence is an imaging system combining the acquisition of single photon nuclear medicine images and images from an x-ray computed tomography system. The x-ray computed tomography subsystems may consist of a whole body multi-slice CT or cardiovascular CT. The cardiovascular subsystem provides coronary imaging that is intended to produce cross-sectional images of the heart, cardiovascular, and peripheral vascular systems by computer reconstruction of x-ray transmission data taken at difference angles and planes. Precedence 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. Precedence 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 Precedence Imaging System should only be used by trained healthcare professionals.

Contraindications for Use:
The Precedence CV Configuration CT subsystem is not indicated for imaging structures that are defined as non-cardiac and non-vascular (including soft tissue and bone).

F. Device Description:
The Precedence SPECT/CT Imaging System 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.

Precedence is constructed from two existing systems, the Skylight SPECT Imaging System and the Brilliance CT with subsystem options of 6, 16, or 64 slice or the CVCT configuration. The Precedence 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 Precedence 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.

Precedence 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 clinical protocols and procedures are that are available on the modified Precedence Imaging System are the same as those on the Predicate Devices Precedence SPECT/CT (cleared as Griffin) (K041218), Predicate Philips Plus CT Scanner (K033326), and the Brilliance CT, Private Practice CV configuration CT Scanner (K042293). The intended use of the CV configuration CT Scanner is limited to the heart, cardiovascular, and peripheral vascular systems. Acquired SPECT and CT images on the Precedence 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. The Precedence CV Configuration CT subsystem is not indicated for imaging structures that are defined as non-cardiac and non-vascular (including soft tissue and bone).

G. Comparison to Predicate Device:
The modified Precedence SPECT/CT Imaging System and the Precedence predicate (K041218) 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 Precedence 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 combined Precedence 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 modified Precedence has added the CT subsystem options of the 64 slice and the CV configuration CT Scanner.

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 Precedence Imaging System is substantially equivalent to the predicate devices, the Precedence SPECT/CT (cleared as Griffin) (K041218), Predicate Philips Plus CT Scanner (K033326), and the Brilliance CT, Private Practice CV configuration CT Scanner (K042293) 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

JUN 8 - 2005

ADAC Laboratories, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K051351
Trade/Device Name: Precedence SPECT/CT Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: KPS and JAK
Dated: May 19, 2005
Received: May 24, 2005

Dear Mr. Christensen:

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): K051351

DEVICE NAME: Precedence SPECT/CT Imaging System

INDICATIONS FOR USE:

Precedence is an imaging system combining the acquisition of single photon nuclear medicine images and images from an x-ray computed tomography system. The x-ray computed tomography subsystem may consist of a whole body multi-slice CT or cardiovascular CT. The cardiovascular subsystem provides coronary imaging that is intended to produce cross-sectional images of the heart, cardiovascular, and peripheral vascular systems by computer reconstruction of x-ray transmission data taken at difference angles and planes. Precedence 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. Precedence 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 Precedence Imaging System should only be used by trained healthcare professionals.

The Precedence CV Configuration CT subsystem is only for the imaging of the cardiovascular 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)

Colleen M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051351