

AUG 23 2006

K062298

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**510(k) SUMMARY SAFETY AND EFFECTIVENESS**

- A. Submitted By: ADAC Laboratories                      Contact: Annie Wright  
540 Alder Dr.    Tel: (408) 468-3779  
Milpitas, CA 95035                                      Fax: (408) 965-2026
- B. Device Trade Name: Apollo Gamma Camera System  
Common Name: Gamma Camera Systems  
Classification Name: Emission Computed Tomography System  
Device Class: 21 CFR 892.1200, Class II  
Product Code: 90 KPS
- C. Date prepared: July 21, 2006
- D. Predicate Device: Forte™ Gamma Camera System (K033254)
- E. Intended Use:

The Apollo Gamma Camera System is intended to produce images depicting the anatomical distributions of single photon emitting radioisotopes within the human body for interpretation by medical personnel.

F. Device Description:

The Apollo Gamma Camera System offers all the features of the Forte™ Gamma Camera System (K033254) while adding the following new features: Caudal/Cephalic Imaging, a second LEHR collimator with improved sensitivity, new CHR collimator, larger Field of View (FOV) with square cornered detectors, < 3-inch brain reach, 3/4" detector crystal (in lieu of 5/8"), Automatic Body Contouring (ABC) with BodyGuard™, MegaBody Mode Imaging, 9-axis ring gantry, extra large patient bore (38" diameter), cart-based semi-automatic exchanger, optional chamfered pallet for low edge attenuation, DICOM MPPS, additional Data Management features (Audit Trail & Patient Privacy), support for new detector, and port server applications from Solaris to LINUX.

Caudal/Cephalic Imaging will allow rotational "tilt" motion of at least one of the detectors about an axis of the detector (parallel to the face of the ring) of at least ±15 degrees. MegaBody mode imaging provides independent variable height positioning of the detectors which includes caudal/cephalic angulations. The detector FOV reach for brain imaging will be less than 3 inches while the detector FOV will be larger (15.5" x 21" instead of 15" x 20") due to the use of the square cornered detectors. In all these cases, the basic functionality of the detector will remain the same (as the detector in the Forte™), while adding detector flexibility to provide a better view of the heart and brain and improve image quality.

The use of 3/4" crystal in lieu of the 5/8" crystal for applications that require higher energy isotopes is now a common trend in the medical device industry. The 3/4" crystal has higher system sensitivity (per NEMA NU-1, Section 3.8) than the 5/8"

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crystal. Another improvement to the system sensitivity is the use of a second type of LEHR collimator in the Apollo System. Higher system sensitivity will improve image quality and may reduce acquisition time and/or applied radiopharmaceutical dosage to the patient. A new collimator will also be used, CHR (aka Rembrandt™ Collimators) which is long-bore collimation that eliminates dead-space in the 90° corner and preserving resolution at depth. This collimator is a variation of the VXGP collimator used in the Forte™ System.

The ABC mode with BodyGuard™ is an addition to the current manual mapping feature available in the Forte System. It is a refinement of the non-circular SPECT and learn-mode TB currently used in Forte™. Also, the BodyGuard™ is the sensing mechanism providing the same functionality as the Collision Avoidance feature in Forte™.

The 9-axis gantry frame provides additional gantry motions designed to improve image quality. Also, the larger bore diameter provides openness for even the largest patients. The cart-based collimator exchanger uses a semi-automatic approach to simultaneously change both collimators. The chamfered pallet option is the same material and basic design as the standard pallet used for the Apollo System. It may be used in lieu of the standard pallet for certain studies that require low edge attenuation.

DICOM MPPS completes the DICOM suite and is a computerized notification stating the type of study being done and when it has been completed. Audit Trail and Patient Privacy are Data Management programs to comply with HIPAA requirements. The remote desktop feature is used in the Forte™ system by remote service personnel. To enhance this feature, remote monitoring will be added to the Apollo System.

The Apollo System is designed to provide extended imaging functionality relative to a ring style gantry. It is designed for single or dual detector nuclear imaging accommodating a broad range of emission computed tomography (ECT) studies. The device includes the gantry frame, display panel, two detectors, a collimator storage unit, an acquisition computer unit (with an optional customer desk), a patient imaging table (includes pallet catcher), and a hand controller. The patient imaging table (pallet) is mechanized for patient loading access and for movement during imaging studies. The table may be removed by the operator for imaging of patients in wheelchairs, beds, or gurneys. The pallet includes removable arm, leg/knee, shoulder and headrest supports for patient positioning during studies that require support.

The Apollo is designed to allow acquisition of a broad range of imaging studies using single or dual detectors. When using either a single detector or dual detectors placed in a relative 90-degree or relative 180-degree positions (as study appropriate), Apollo can be used to perform static, dynamic, gated, total body, circular-orbit and non-circular orbit SPECT studies, coincidence studies, gated SPECT (circular and non-circular) studies, computer-programmed protocol strings, and reference scans (dual detectors only). SPECT and total body acquisitions are routinely acquired with two detectors. There are some planar procedures such as bone statics and lung scan that

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also use two detectors. There are many additional nuclear medicine procedures that only use one detector at a time. These single detector procedures are typically renal, gastric emptying, hepatobiliary, flow studies, GI bleed, thyroid, and delayed static views.

G. Technological Comparison:

The modified Apollo Gamma Camera System and Forte™ Gamma Camera System have identical intended use and indications for use. The Apollo and the Forte™ are technologically equivalent. They have the same main mechanical and electrical components. All the features (except for the attenuation correction and Outer Room (related to detector 2 rotation)) provided on the Forte™ are provided on the Apollo. New features include: Caudal/Cephalic Imaging, second LEHR collimator with improved sensitivity, new CHR collimator, larger Field of View (FOV) with square cornered detectors, < 3-inch brain reach, 3/4" detector crystal (in lieu of 5/8"), Automatic Body Contouring (ABC) with BodyGuard™, MegaBody Mode Imaging, 9-axis ring gantry, extra large patient bore (38" diameter), cart-based semi-automatic exchanger, optional chamfered pallet for low edge attenuation, DICOM MPPS, additional Data Management features (Audit Trail & Patient Privacy), support for new detector, and port server applications from Solaris to LINUX.

H. Conclusion

The Apollo Gamma Camera System is substantially equivalent to the predicate device Forte™ based upon identical indications for use, technological comparison and overall system performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 28 2006

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

ADAC Laboratories, Inc.  
% Mr. Morten Simon Christensen  
Staff Engineer & FDA Office Coordinator  
Underwriters Laboratories, Inc.  
455 East Trimble Road  
SAN JOSE CA 95131

Re: K062298  
Trade/Device Name: Apollo Gamma Camera System  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission computed tomography system  
Regulatory Class: II  
Product Code: KPS  
Dated: August 4, 2006  
Received: August 8, 2006

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.



*Protecting and Promoting Public Health*

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). 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,



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 STATEMENT**

510 (k) NUMBER (IF KNOWN): K062298

DEVICE NAME: Apollo Gamma Camera System

SPONSOR NAME: ADAC Laboratories

**INDICATIONS FOR USE:**

The Apollo Gamma Camera System is intended to produce images depicting the anatomical distributions of single photon emitting radioisotopes within the human body for interpretation by medical personnel.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

David R. Legerson  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K062298