510(k) SUMMARY SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories
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B.

Device Trade Name:	Forte™ 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: September 18, 2003

D. Predicate Device: Forte™ Gamma Camera System (K982911)

E. Intended Use:

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

F. Device Description:

The modified Forte Gamma Camera System offers all the features of the existing Forte Gamma Camera System (K982911) while expanding the Concurrent Imaging feature for Multi-Energy/Multi-Isotope Imaging and the addition of DICOM to the acquisition system. The basic underlying algorithms for concurrent imaging remain the same. Software modifications to the Multi-Energy/Multi-Isotope application extend the current functionality to include acquisition of more image events simultaneously. Acquisition data can be exported to the Pegasys or any other processing station via DICOM by translating image data from the native XML format to a DICOM 3.0 complaint format. The addition of DICOM to the acquisition software will enhance workflow by providing DICOM Worklist and the capability to import patient information for scheduling purposes. The DOS-based user interface in Atlas acquisition system (predicate) is replaced by a Java based graphical user interface JETStream™. The Java graphical user interface provides a modern graphics presentation as opposed to the DOS text based interface of the predicate. In addition, P-scope (patient positioning/count rate) and gantry display information are now available on a touch screen for easy accessibility.

The Forte is designed to provide extended imaging functionality relative to a ring style gantry. The Forte is designed for single or dual detector nuclear imaging accommodating a broad range of emission computed tomography (ECT) studies. The device includes a gantry frame, display panel, two detectors, a collimator storage structure with an acquisition computer unit, a patient imaging table, and a remote hand controller. The gantry is "open" so that a high degree of imaging flexibility is available to image patients sitting, standing or lying down, with or without the included patient imaging table. The patient imaging tables are mechanized to allow for patient loading access and then raised to

an imaging height. The imaging pallet includes removable arm, leg, breast, and headrest supports for patient positioning during studies that require support.

The Forte 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), Forte 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 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 Forte™ Gamma Camera System and existing Forte Gamma Camera System have identical intended use and indications for use. The modified Forte and the existing Forte are technologically equivalent. They have the same main mechanical and electrical components. All the features provided on the existing Forte are provided on the modified Forte. Acquisition software changes consist of: replacement of the predicate Atlas with the JETStream, the expanded feature of Concurrent Multi-Energy/Multi-Isotope Imaging, and DICOM Export/Worklist. In addition, the P-scope (patient positioning/count rate) and gantry display information shall be available on a touch screen.

H. Conclusion

The modified Forte™ 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

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

Re: K033254
Trade/Device Name: Forte™ Gamma Camera System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: October 6, 2003
Received: October 8, 2003

Dear Ms. Klinker:

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

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K033254

DEVICE NAME: Forte™ Gamma Camera System

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033254

(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_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)