510(k) SUMMARY SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035

Contact: Joy M. Sacmar
Tel: (408) 468-3053
Fax: (408) 468-3050

B. Device Trade Name: Syntegra™

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: April 26, 2004

D. Predicate Device (s):

Manufacturer	Product Name	510(k) No.
Philips Medical Systems	Gemini 16	K032036

E. Intended Use:

Syntegra™ is a software application for multi-modality image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals

F. Device Description:

Syntegra™ is a software application for multi-modality image registration and diagnostic fusion. This application exists within the predicate device, Gemini 16 (K032036). The Gemini 16 is an imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT). This PET/CT device includes the processing station and applications contained within, such as image fusion. Syntegra™ may be offered as a standalone software application that has the capability to be utilized on any PC image processing workstations meeting the minimum hardware requirements to support the application.

Registration is the process of aligning two or more images from the same patient so that physical positions within each image are coincident. The images may be from the same imaging modality or different imaging modalities.

Fusion display is the visual combination of two image data sets that allows the data sets to be displayed simultaneously in a blended mode in the same screen window. The level of blending is determined by user adjustable opacity values assigned to each data set. A common application of fusion display is the combination of physiological data from SPECT images and anatomical information from CT images.

Images are registered and displayed in a fused format to provide combined functional and anatomical data. The images are presented using various three-dimensional rendering techniques such as multi-planar reformatting, surface rendering with cut-planes, and maximum intensity projections.

Syntegra also offers Region of Interest tools. These are tools, which allow a user to draw two-dimensional contours around areas of interest on the transaxial image planes. The contours may then be exported to Radiation Therapy Planning systems, which use the two dimensional contours to generate three-dimensional volumes, which may be used in therapy planning.

The application operates on WindowXP/Intel Pentium computer systems with the following minimum requirements:

- Graphics Card: 24/32 bit color, support for 1400x1162 screen resolution
- RAM: 1 GB
- Processor: Pentium IV and above
- Clock Speed: 1GHz clock speed

G. Technological Comparison:

Syntegra and the image fusion software application within the predicate, Gemini (K032036), have similar indications for use and utilize similar methods for registration, fusion, and display of images from different modalities. Syntegra, like the predicate device also has the tools and capability to display the combined images for a more comprehensive image. The similarities and differences between the Syntegra and the predicate device are described in detail in Section E of this pre-market notification.

H. Conclusion:

Syntegra is substantially equivalent to the image fusion software application from the following predicate device, Gemini (K032036), based on similar intended use and technological comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2004

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

Re: K041182
Trade/Device Name: Syntegra™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: May 4, 2004
Received: May 6, 2004

Dear Ms. Drew:

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

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K041182

DEVICE NAME: Syntegra™

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

Syntegra™ is a software application for multi-modality image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V (Per 21 CFR 801.109) OR Over-The-Counter-Use_____ (Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041182