DEC 1 9 2003

K033782

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

***General Information***

A. ***Submitter/ Contact Person***:


Philips Medical Systems (Cleveland), Inc.
595 Miner Rd.
Cleveland, OH 44143

Christof Littwitz
Tel: (440) 483-3585
Fax: (732) 352-6897


B. ***Device Trade Name***: Allegro Imaging System

***Common Name***: Positron Emission Tomography

***Classification Name***: System, Emission Computed Tomography, (892.1200)

***Device Class***: 21CFR 892.1200, Class II

***Product Code***: 90 KPS

C. ***Date prepared***: November 24, 2003

D. ***Predicate Device***: Allegro Imaging System (K003434, 11/16/2000)

E. ***Performance Standards:*** NEMA NU-2

F. ***Intended Use:***

The device is a Positron Emission Tomography (PET) Imaging System. It is intended to produce images depicting the anatomical distributions of single photon and positron emitting radioisotopes with the human body for interpretation by medical personnel.

***G. Device Description:***

The Allegro Imaging System is a Positron Emission Tomography (PET) system, a nuclear medical imaging system with capabilities to acquire, process, and display clinical images that can be utilized in both conventional, fixed installations or mobile environments. It is intended to produce attenuation and non-attenuation corrected images depicting the anatomical distribution of single photon and positron emitting radioisotopes within the head, body, or total body for interpretation by medical personnel. The system allows the reconstruction of high-resolution, three-dimensional, static, gated, and dynamic images of biochemical and metabolic processes.

***H. System Performance Test/ Summary of Studies:***

To minimize electrical, mechanical and radiation hazards, Philips Medical System adheres to recognized and established industry practice. Electrical and mechanical safety is assured by adherence and certification to the applicable standards in the IEC 60601-1 series. The device performance was measured in accordance with NEMA-NU2 standard.

## *I. Comparison to Predicate Device*

The Allegro Imaging System software is an evolution of the features and functionalities of the existing Allegro Imaging System (K003434, 11/16/2003). Design modifications include enhancements in DICOM functionality, patient positioning capabilities, and cardiac imaging and analysis. Similarities and differences between the device and its predicate are described within the 510(k) submission.

In conclusion, the device is substantially equivalent to the predicate device 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

DEC 1 9 2003

Philips Medical Systems, Inc.
% Mr. Juergen Welte
Responsible Third Party Official
TUV Rheinland of North America
1279 Quarry Lane, Suite A
PLEASANTON CA 94566

Re: K033782
Trade/Device Name: Allegro Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: December 2, 2003
Received: December 4, 2003

Dear Mr. Welte:

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*): K033782

**DEVICE NAME:** Allegro Imaging System

**INDICATIONS FOR USE:**

The device is a Positron Emission Tomography (PET) Imaging System. It is intended to produce images depicting the anatomical distributions of single photon and positron emitting radioisotopes with 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 ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Seyran

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033782