Photon² 14350 S.W. 142nd Ave., Miami, FL. 33186
Phone: 305-234-0836

K033001

DEC 2 4 2003

SECTION G
510(K) SUMMARY

21CFR 807.92

1.0 Introduction

This 510(k) Premarket Notification has been prepared to demonstrate that the APEX XL-4, manufactured by Photon², is substantially equivalent to the NC Systems, Inc. CardioSPECT SC which has previously been reviewed and approved via the 510(k) premarket notification process (K021823).

2.0 Submitter Identification

2.1 Applicant Name & Address:

Transphoton Corporation
(dba Photon²)
14350 S.W. 142nd Avenue
Miami, FL 33186
Phone: 305-234-0836
Fax: 305-234-2398

2.2 Contact Person:

Scott Jennings
IBIS, Inc.
37 Electric Avenue
Lunenburg, MA 01462
Phone: 978-985-2532
Fax: 978-582-4544

2.3 Manufacturing Site:

Mediso, Ltd.
Alsotorokvesz 14
H-1022 Budapest, Hungary

2.4 Date of Submission:

September 30, 2003

3.0 Device Identification

3.1 Device Proprietary Name:

Photon² APEX XL-4

3.2 Common Name:

Gamma Camera – SPECT Imaging System

3.3 Classification Name:

Emission Computed Tomography System (ECT)

3.4 Classification Panel:
Radiological

3.5 Regulatory Class:
Class II

3.6 Regulation Number:
21CFR 892.1200

3.7 Product Code:
90KPS

4.0 Identification of Equivalent Device

4.1 Predicate Device 510(k) Number:
K021823

4.2 Predicate Device Identification:
Proprietary Name: NC Systems, Inc. CardioSPECT SC
Device Name (common): Gamma Camera-SPECT Gamma Camera
Classification Name: Emission Computed Tomography System (ECT)
Regulation Number: 21CFR 892.1200
Regulatory Class: II
Product Code: 90KPS

4.3 Predicate Device Description:
The predicate device, NC Systems, Inc. CardioSPECT SC, is a device with components that have substantially equivalent specifications, safety, effectiveness, and intended use as the Photon² APEX XL-4:

- The CardioSPECT SC is a scintillation detector, NaI, system with PMT light gathering capacity. The CardioSPECT SC has one detector both with the ability to rotate these detectors around the patient. The system uses a collimator on the detector to permit spatial image resolution of the gamma photons emitted from the patient. The collimators lock in place. There is no built-in radioactive scanning source and none is required. The CardioSPECT SC is capable of both Planar (Class I) and SPECT or ECT (Class II) operation. The acquisition/processing computer is an approved system sold and supported by NC Systems, Inc. but manufactured by Segami Corporation.
- The detector electronics, mechanical components, software, and the manufacturing specifications of the applicant system (the APEX XL-4) are substantially equivalent to the CardioSPECT SC, the legally marketed device.
- Detailed specifications for the predicate device are provided in Section C.

5.0 Intended Use

The intended use of the APEX XL-4 is to acquire nuclear medicine gamma camera output data for previously-approved Elscint APEX Gamma Camera systems. This acquisition is performed in the same manner as the corresponding components of the equivalent device, K021823.

6.0 Determination of Substantial Equivalence

The APEX XL-4 Interface has been compared to the corresponding components of the legally marketed CardioSPECT SC System and been determined to be substantially equivalent:

- The intended use of the applicable components in the two devices is identical.
- The specifications for each device are compared in Section C.
- The labeling for each device are equivalent. Refer to Section D.
- The conclusion of tests performed and clinical images obtained demonstrate that the subject device (APEX XL-4) is as safe and effective as the legally marketed device (CardioSPECT SC). Refer to Section E.

Thus, we conclude that the APEX XL-4 is substantially equivalent to the predicate device and that no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2003

Transphoton Corporation
% Mr. Scott Jennings
IBIS, Inc.
37 Electric Avenue
LUNENBURG MA 01462

Re: K033001
Trade/Device Name: APEX XL-4
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: September 24, 2003
Received: September 30, 2003

Dear Mr. Jennings:

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

510(k) Number (if known): K 03 30 01

Device Name: APEX XL – 4

Indications For Use:

The Apex XL-4 is intended for use as an acquisition of Nuclear Medicine SPECT and Planar Gamma Camera images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033001

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____