SECTION G
510(K) SUMMARY

In accordance with 21CFR 807.92

APR 24 2007

1.0 Submitter Information

Name: Transphoton Corporation
(dba Photon^2)

Address: 14350 S.W. 142nd Avenue
Miami, FL 33186

Phone: 305-234-0836
Fax: 305-234-2398

Contact Person: Brant Wigger, Chief Operations Officer

Date of Submission: February 28, 2007

2.0 Device Identification

Name of Device: C! SPECT Imaging System

Common Name: Gamma Camera – SPECT Imaging System

Classification Name: Emission Computed Tomography System (ECT)

3.0 Predicate Devices

1. Myolight – GE Medical Systems F.I. Haifa [**K033874**]
2. CardiArc Ltd. – CardiArc SPECT Imaging Device [**K053062**]
3. Transphoton Corporation – APEX XL-4 [**K033001**]

4.0 Intended Use / Indications for Use

For use in the acquisition of Single Photon Emission Computed Tomography (SPECT) and Planar gamma camera images.

5.0 Technological Characteristics

The C! SPECT Imaging System is an open gantry (with no external moving parts), upright seated device with an integrated patient chair, an acquisition station, two detectors, and hardware and software components. The patient chair is mechanized to accommodate patient loading and centering in the detector field of view.

Thus, the C! SPECT Imaging System raises no new issues of safety or efficacy.

6.0 Performance Testing and Data

Performance testing was performed using NEMA NU1 phantoms, under the NEMA Standard test protocols. In all cases, performance of the C! device met or exceeded that of predicate devices.

Clinical images were obtained using the C! in human subjects. Tomographic image quality was at least equal to images produced by reference predicate devices.

Furthermore, electrical safety testing has been performed and found to meet applicable standards and defined acceptance criteria.

7.0 Substantial Equivalence

The C! SPECT Imaging System has the same intended use, similar principles of operation, and consistent technological characteristics as the predicate devices. Thus, the C! is substantially equivalent to the predicate devices and no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 24 2007

Mr. Brant Wigger
Chief Operations Officer
Transphoton Corporation (dba Photo2)
14350 S. W. 142nd Avenue
MIAMI FL 33186

Re: K070589
Trade/Device Name: C!
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 28, 2007
Received: March 1, 2007

Dear Mr. Wigger:

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.

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

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Indications for Use Form

510(k) Number (if known): K070589

Device Name: C!

Indications For Use:

The C! is indicated for use in the acquisition of Single Photon Emission Computed Tomography (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)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070589