K091073

MAY 14 2009

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name
Proprietary Device Name: Xpress.cardiac & Xpress3.cardiac including Attenuation & Scattering Corrections

Establishment Name and Registration Number of Submitter
Name: UltraSPECT Ltd.
Corresponding Official: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

Device Classification

Product Code:	KPS
Subsequent Product Code	LLZ
CFR section:	892.1200
Panel Identification:	Radiology
Device Description:	Emission computed tomography system
Classification:	Class II Product

Reason for 510(k) Submission
Special 510(k) Submission

Identification of Legally Marketed Predicate Devices
Xpress.cardiac - K080784, Xpress3.cardiac - K081201
Xeleris - K051673

Device Description
The Xpress.cardiac & Xpress3.cardiac are image processing systems, which are interfaced to gamma cameras. Gamma camera cardiac, fast acquired, data are reconstructed by the devices, which utilize parallel and non – parallel beams and produce high resolution images. The images can be transferred to any other PACS device, which is DICOM or Interfile compatible. The devices have been modified by including Attenuation and Scattering Corrections (ACSC).

Intended Use of Device
The WBR Xpress3.Cardiac and WBR Xpress.Cardiac including the Attenuation & Scattering Corrections are indicated for the acquisition, formatting and storage of scintigraphy camera output data. They are capable of processing and displaying the acquired information in traditional formats, as well as in pseudo three dimensional renderings, and in various forms of animated sequences, showing kinetic attributes of the imaged organs

Safety & Effectiveness
The device has been designed, verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that reconstructed and ACSC corrected images are equivalent in comparison to images that are reconstructed and ACSC corrected by predicate Xeleris device.

Substantial Equivalency
It is UltraSPECT opinion that the modified Xpress.cardiac & Xpress3.cardiac are substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

UltraSPECT Ltd.
% Mr. Dan Laor
Quality & Regulatory Advisor
Quasar Quality Ltd
6 Sireni, Haifa 32972
ISRAEL

Re: K091073
Trade/Device Name: Xpress.Cardiac & Xpress3.cardiac including Attenuation & Scattering Corrections
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and LLZ
Dated: April 12, 2009
Received: April 14, 2009

Dear Mr. Laor:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) 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 892.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). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091073

Device Name: Xpress.cardiac & Xpress3.cardiac including Attenuation & Scattering Corrections

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 K091073