K080784

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

Device Name

Proprietary Device Name: WBR Half Dose.

Establishment Name

UltraSPECT Ltd.

APR - 2 2008

Submission contact person:
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 Equivalent Devices

WBR Xact.cardiac & Xpress.cardiac - K050815

Device Description

The WBR Half dose is a modification of labeling of the legally marketed device. The device is an image processing system, which is interfaced to gamma cameras, processes the cameras' acquired data utilizing 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 modified labeling claims that, as far as the acquired information density is maintained, the same image quality is achieved either by fast acquisition or by reduced dose acquisition modes.

Intended Use of Device

The WBR Half dose is indicated for the acquisition, formatting and storage of scintigraphy camera output data. It is 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 image organs

Safety & Effectiveness

The device has been designed, verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that reconstructed images are equivalent or of better resolution comparing to images that are reconstructed by filter back - projection. No adverse affects have been detected.

Substantial Equivalency

It is UltraSPECT's opinion that the WBR Half Dose and the Xact.cardiac & Xpress.cardiac are substantially equivalent in terms of safety and effectiveness to the above predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR - 2 2008

UltraSPECT Ltd.
% Mr. Dan Laor
Regulatory Consultant
Sireni 6
Haifa 32972
ISRAEL

Re: K080784
Trade/Device Name: WBR Half Dose
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: March 9, 2008
Received: March 20, 2008

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.

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 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indications for Use

510(k) Number (if known): K080784

Device Name: WBR Half Dose

Indications For Use:

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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 K080784