K103710

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

Device Name

Proprietary Device Name: WBR Xpress.PET

Establishment Name and Registration Number of Submitter

Name: UltraSPECT Ltd.
Corresponding Official: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

JAN 19 2011

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

WBR Xpress. Bone - K040370 & K080784
WBR Attenuation and Scattering Correction - K091073
Work station of the GE Discovery LS - K040172

Device Description

The WBR Xpress.PET is image processing system, which is interfaced to PET/CT. Fast acquired, data are reconstructed by the device, which utilizes parallel and non – parallel beams and produce high resolution images. The images can be transferred to any other PACS device, which is DICOM compatible. The device includes Attenuation and Scattering Corrections (ACSC).

Intended Use of Device

The WBR Xpress.PET including the Attenuation & Scattering Corrections is indicated for the acquisition, formatting and storage of scintigraphy 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 CT/PET device.

Substantial Equivalency

It is UltraSPECT opinion that the modified Xpress.PET is substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Dan Laor
Quality & Regulatory affairs Advisor
UltraSpect Ltd.
6 Sireni
Haifa 32972
ISRAEL

JAN 19 2011

Re: K103710
Trade/Device Name: WBR Xpress.PET
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: December 13, 2010
Received: December 20, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k103710
Device Name: WBR Xpress.PET

Indications for Use:
The WBR Xpress.PET including the Attenuation & Scattering Corrections is indicated for the acquisition, formatting and storage of scintigraphy 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 imaged organs

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103710