K040370

MAR 1 1 2004

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

Device Name

Proprietary Device Name : WBR - fHR , WBR - fWB.

Establishment Name and Registration Number of Submitter

Name: UltraSPECT Ltd.
Corresponding Official: Dan Laor
Building 30, MATAM
Haifa, 31905
Israel

Device Classification

Classification Code:	90 KSP
Panel Identification:	Radiology
Classification Name:	Image processing (per 21CFR 892.1200)
Common Name:	SPECT Imaging system
Classification Class:	Class II Product

Reason for 510(k) Submission

Special 510(k) Submission

Identification of Legally Marketed Equivalent Devices

K031874 WBR - WB

Device Description

The WBR – fHR and the WBR – fWB are image processing systems, which are interfaced to gamma cameras. Camera- fast acquired data is reconstructed by the WBR – FHR or processed by the WBR – fWB, 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.

Intended Use of Device

The WBR- fHR and the WBR – fWB are indicated for acquiring gamma camera output data. It is capable of processing the acquired information, store it and display the resulted images in traditional formats.

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 the images that are back - projection reconstructed. No adverse affects have been detected.

Substantial Equivalency

It is UltraSPECT opinion that the WBR- fHR and the WBR – fWB are substantially equivalent in terms of safety and effectiveness to the above predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2004

Mr. Dan Laor
Quality Manager
UltraSPECT, Ltd.
P.O. Box 15010, MATAM
Haifa, 31905
ISRAEL

Re: K040370
Trade/Device Name: WBR-fHR, WBR-fWB
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: February 8, 2004
Received: February 17, 2004

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 (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): K040370

DEVICE NAME: WBR – fHR, WBR - fWB

INDICATION FOR USE: The WBR – fHR, WBR - fWB 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 image organs.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040370