1 GENERAL INFORMATION

DEC 15 2004

Company and Contact Details:

Submitters Name:			Establishment Registration Number:	
Mirada Solutions Ltd			3003493157	
Address:			Tel.	Fax.
Level 1, 23-28 Hythe Bridge Street			44-1865-265 500	44-1865-265 501
City:	State:	Post code:	Country:	
Oxford	OXON	OX1 2ET	United Kingdom	
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Michelle Sawyer	VP Quality& Regulatory Affairs	michelle.sawyer@mirada-solutions.com		
Contact Name in US:	Contact Title in US:	Contact E-Mail Address in US:		
Ms. Maria Ebio	Regulatory Affairs Manager	maria.ebio@ctimi.com		
Telephone Number in the US:	Fax Number in the US:	Contact Address in US:		
865-218-2534	865-218-3019	810 Innovation Drive, Knoxville, TN 37932		

Proprietary name of Device: Scenium

Common Name of Device: Emission Computed tomography system, Product Code: 90KPS

Classification: Class II: Sec. 21 CFR. 892.1200

Performance Standard: 21 CFR Subchapter H, Emission Computed tomography system

Predicate Device(s):

510(k) No.	Trade name	Manufacturer	Component Applicable to
K041022	NeuroQ™	Syntermed, Inc	Display and analysis program
K041543	GE Discovery ST	GE Healthcare	Display and analysis program

Reason for submission: First market clearance application for the device.

Device description:

Scenium display and analysis software enables visualization and appropriate rendering of multi-modality data, providing a number of features which enable the user to process the acquired image data.
The software is post processing and does not control the scanning features of the system.

Summary of intended uses:
The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET scans. The software is deployed via medical imaging workstations and is organised as a series of workflows which are specific to use with particular drug and disease combinations.
The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest facilitating comparison with existing scans derived from FDG-PET studies.

Technological characteristics:
This software is similar in uses and applications to those of the predicate devices. Both this and the predicate devices are used to assist the Clinician with the visual evaluation, assessment and quantification of pathologies derived from PET scans.

Safety and effectiveness concerns:
The device is designed and manufactured under Quality system regulations as outlined in 21 CFR § 820 .All requirements of the Emission Computed tomography system Standard, as outlined in 21 CFR 820.1200 have been met and additionally the software is in compliance with the requirements of ISO 14971 – Medical Devices application of risk management.

Substantial equivalence:
Based upon the above considerations, Mirada believes that the Scenium software is substantially equivalent to the chosen predicate devices. The Scenium software and the predicate devices are all post-processing and provide the same features of visualization and numeric data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2004

Mirada Solutions Ltd.
% Ms. Maria Ebio
Regulatory Affairs Manager
CTI Medical Imaging
810 Innovation Drive
KNOXVILLE TN 37932

Re: K042863
Trade/Device Name: Scenium display and analysis software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 KPS and LLZ
Dated: October 18, 2004
Received: October 18, 2004

Dear Mr. Ebio:

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.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" (21 CFR 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 (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

FDA INDICATION FOR USE FORM

Ver/ 3 - 4/24/96

Applicant: Mirada Solutions Ltd.

510(k) Number (if known): K042863

Device Name: Scenium

Indications for Use:
Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET scans.
The software is deployed via medical imaging workstations and is organised as a series of workflows which are specific to use with particular drug and disease combinations.
The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest facilitating comparison with existing scans derived from FDG-PET studies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescriptive Use ✓ OR Over – The – Counter Use__

(Per 21 CFR 801.109)

(Per 21 CFR 801.109) (Optional Format 1-2-96) Truthful and Accurate Statement

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042863

