APR 26 2002 K020546

FUSION7D 510(K) SUMMARY

Date: 7th February, 2002

Submitters Name: Mirada Solutions Ltd.
Submitters Name: Oxford Centre for Innovation.
Mill Street, Oxford OX2 OJX, United Kingdom.
Submitters Contact: Dr. Nick Cerneaz, VP Engineering.
Tel: 44-1865-811125 Fax: 44-1865-793165
Submitters Contact USA: Mr. Roger Barnes, rogerb@cswnet.com
Tel. 501 525 86 39 Fax: 501 525 86 12

Device Proprietary Name: Fusion7D
Common Name of Device: Multi-modality Registration Workstation Software
Classification Name: Class II: Picture Archiving and Communications System (892.2050) Product Code: **LLZ Image Processing System**

Critical Definitions:

Image Registration	The alignment of one or more [medical] images to a reference image in order to facilitate geometric comparison. This is a numerical operation that results in the computation of an explicit mathematical transformation between every point in the registered image sets.
Image Fusion	Registration forms the basis of image fusion in the sense that the geometrical alignment of images is a prerequisite. The notion of "fusion" takes this a step further by considering how to visualize the content of different images representing the same object [organ, anatomical region, etc.]. Such techniques include the use of overlays, semi-transparent renderings, etc.

NOTE: In the context of this application, the term "registration" and "fusion" may be used interchangeably to describe geometric alignment of images and subsequent visualization.

Device description:

Fusion7D is a software program running on a PC platform, which brings into alignment (registers) pairs of images from different imaging modalities. Fusion7D also includes functionality to read, display, and save the original volumetric data and the results of the registration operation by means of a graphic user interface that includes visualization, file browsing and control of input and output as described in the following text.

Registration Engine
Medical images can be divided into anatomical images (e.g. CT and conventional MRI), and functional images (e.g. SPECT and PET). Fusion7D provides two registration solutions: 1. It enables the comparison of pairs of anatomical images (to assess changes in anatomical structures) and 2. It correlates the structures seen in an anatomical dataset with the activity detected in functional images.

Fusion7D is therefore useful to register the following pairs of datasets:

Anatomical to Anatomical	
Source	*Target*
MRI	MRI
MRI	CT
CT	CT

Anatomical to Functional	
Source	*Target*
MRI	PET
MRI	SPECT
CT	PET
CT	SPECT

The registration operation can be a) *manual:* whereby the user defines the transformation that brings the two datasets into as close alignment as possible, b) *semi-automatic*: in which the user inputs a series of landmarks in one dataset and the software provides matching landmarks in the other, and c) *automatic:* in which the software requires no user input and finds the transformation between the two datasets based on the characteristics of the images. In all these cases the transformation is limited to a rigid body deformation (i.e. 3D translation and rotation).

Data/Image Browsing and Visualization

The Fusion7D software incorporates standard visualization facilities to visualize the input DICOM data and the results of the registration operations. This simple visualization GUI includes:

- orthogonal and any-plane slicing of the volumetric data (but no 3D reconstruction),
- whole and region of interest zooming,
- panning,
- window and level controls,
- image overlays for which the transparency, threshold and colormap is user controlled.

The Fusion7D software allows the registration results to be displayed in a variety of ways including: the overlay of one dataset on another, the simultaneous binding of cursors in two volumes and the generation of a split pane image.

Intended Use:

Fusion7D registers pairs of anatomical and functional volumetric images (e.g. MRI-SPECT, MRI-PET, CT-SPECT, CT-PET), or pairs of anatomical volumetric images (e.g. MRI-MRI, CT-CT and MRI-CT) as a means to ease the comparison of image data. The result of the registration operation aims to help the clinician obtain a better understanding of the joint information that would otherwise have to be compared visually. This is useful for a wide range of clinical and therapeutic applications. It is important to note that the clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures, including visual comparison of the separate unregistered images. Fusion7D is a complement to these standard procedures.

Predicate Devices:

510(k) No.	Tradename	Manufacturer	Component Applicable to
K010336	Advantage Windows CT/PET Fusion	General Electric	Anatomical to Functional Registration Component
K983256	Advantage Windows Fusion	General Electric	Anatomical to Anatomical Registration Component
K992654	Plug 'n View 3D	Voxar	Visualization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2002

Mirada Solutions Ltd.
% Mr. Roger W. Barnes
Regulatory Consultant
342 Sunset Bay Road
HOT SPRINGS AK 71913

Re: K020546
Trade/Device Name: Fusion 7D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 7, 2002
Received: February 19, 2002

Dear Mr. Barnes:

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 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 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:

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" (21 CFR Part 807.97). 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

FDA INDICATION FOR USE FORM

Ver/ 3 - 4/24/96

Applicant: Mirada Solutions Ltd.

510(k) Number (if known): K020546

Device Name: Fusion7D

Indications For Use:

Fusion7D registers pairs of anatomical and functional volumetric images (e.g. MRI-SPECT, MRI-PET, CT-SPECT, CT-PET), or pairs of anatomical volumetric images (e.g. MRI-MRI, CT-CT and MRI-CT) as a means to ease the comparison of image volume data by the clinician. The result of the registration operation aims to help the clinician obtain a better understanding of the joint information that would otherwise have to be compared visually. This is useful for a wide range of clinical and therapeutic applications. It is important to note that the clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures including visual comparison of the separate unregistered images. Fusion7D is a complement to these standard procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) David L. Ilgenfritz

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020546

Prescription Use ✓