K061418

510(k) Summary

Quantiva™

JUL 21 2006

1 May 2006

Sponsor	**Consultant**
Tomographix IP Ltd. 33 Hazelton Avenue, Suite 88 Toronto, Ontario M5R 2E3 Voice 416 638 3103 Fax 416 924 5884 audrius@tomographix.com	Mr. Richard Keen Compliance Consultants 1151 Hope Street Stamford, CT 06907-1659 203 329 2700 F 203 329 2345 rkeen@fda-complianceconsultants.com
Proprietary Name:	**Quantiva™**
Common Name	**Quantiva™**
Device Classification Name	System, Image Processing Radiological
Classification Name:	Picture Archiving and Communication System
Product Code	LLZ
Device Classification	Class II
Establishment registration No.	Not applicable (foreign manufacture)
Predicate Device	Fusion7D, K033955, Mirada Solutions Ltd.

Trademark Notice: All Trademarks used other than those of ***Tomographix IP Ltd.*** are registered to their respective owners.

Confidentiality notice: All data contained in this application and all appendixes provided with his appendix or aided trade secrets or proprietary data which the sponsor requests are treated in accordance with law.

Device Description

The **Quantiva™** is a Class II software application intended to co-register anddisplay fused PET plus CT images enabling a qualified radiologist or radiological technologist to visualize 2D & 3D multimodal (CT and PET) medical image data. The qualified user may process, render, view, store, and print DICOM 3.0 compliant medical image data within the system and/or across computer networks utilizing standard P.C. hardware and software.

Intended Use

Quantiva™ software system coregisters pairs of anatomic (CT) and functional (PET) volumetric image data and displays the fused images to provide additional combined anatomic plus functional image information to the diagnosing radiologist.

Technological Characteristics and Substantial Equivalence

This system creates a rigid and non-rigid fusion of two common diagnostic images. This process results in more diagnostic information than is provided by current methods. The **Quantiva™** software has benefited from design, development, testing and production procedures that conform to Quality Systems. ***Tomographix IP Ltd.*** has determined that the **Quantiva™** software has fundamentally the same indications for use as the predicate device.

Performance Testing

Information submitted in this premarket notification for the **Quantiva™** software includes results of performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 21 2006

Tomographic IP Ltd.
% Mr. Richard Keen
Responsible Third Party Official
Compliance Consultants
1151 Hope Street
STAMFORD CT 06907-1659

Re: K061418
Trade/Device Name: Quantiva™ software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 1, 2006
Received: May 22, 2006

Dear Mr. Keen:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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): _K061418_

Device Name: Quantiva™ software

The **Quantiva™** is a software application intended to co-register and display 2D & 3D multimodality (CT & PET) medical images data. The medical practitioner can visualize, process, render, view, store, print and distribute DICOM 3.0 compliant medical image data within the system and/or across computer networks as distributed locations utilizing standard P.C. hardware.

The volume and linear measurement functions are intended for evaluation and quantification of tumor measurements, location/displacement study, analysis and evaluation of both hard and soft tissue. The software also supports interactive segmentation of the region of interest, automated contouring of multi-slice ROI and labeling of avoidance structures during evaluation.

Typical users of **Quantiva™** are for trained professionals (including but not limited to: radiologists, clinicians and technicians). When interpreted by a trained physician, reviewed images may be used as an element for diagnosis.

The **Quantiva™** is indicated for use when it is necessary to acquire, record, review and distribute these images. The **Quantiva™** is a prescription device. The labeling, instructions and user operations are designed for trained, licensed medical professionals.

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061418

Prescription Use __XXX_____ 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 Device Evaluation (ODE)