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U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cyc)

FOLDER: K120187 - 416 pages

COMPANY: IGT LLC DBA EIGEN (IGTLLCDBAEIGE)

PRODUCT: SYSTEM, IMAGE PROCESSING, RADIOLOGICAL (LLZ)

SUMMARY: Product: MULTI-MODALITY IMAGE FUSION

DATE REQUESTED: Oct 25, 2013

DATE PRINTED: Oct 25, 2013

Note: Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K120187

510(k) Summary

APR - 6 2012

Submitter's Name: IGT, LLC dba Eigen
Submitter's Address: 13366 Grass Valley Avenue, Grass Valley, CA 95945
Submitter's Telephone: 530-274-1240
Contact Name: William Mandel

Date Summary was Prepared: 21 Oct 2011
Trade or Proprietary Name: Multi-Modality Image Fusion
Common or Usual Name: Multi-Modality Image Fusion
Classification Name: System, Image Processing, Radiological, LLZ
Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
Syntegra	K041182
UniSyn	K081987
Aegis Navigation	K093672
Abaris	K053610

Intended Use

Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

Description of the Device and Summary of the Technological Characteristics:

Multi-Modality Image Fusion (MMIF) is software, which comprises of two software components, which is referred to as offline and online. The offline component pertains to the preparation of gland and suspected lesion boundaries on a DICOM image file days or hours prior to the biopsy procedure. The online component fuses the DICOM image files, which were, prepared on the offline component, with a snap shot incoming TRUS image. Each of the two software components can work together or independently.

Offline Software

The offline software can delineate suspected areas of interest using visualization and save this data in a standard format, e.g. as a surface mesh in VTK or STL format. Furthermore, the

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offline software can optionally delineate the gland boundary from a DICOM image, or other volumes where the boundary can be easily observed. This addition data is also saved in a standard format, e.g. surface mesh in VTK or STL or as a binary volume. This software would be typically executed by Radiologists.

Online Software

The online unit software is designed to fuse two images by entering a fusion mode and load the DICOM image and the boundary data provided by the offline unit. The online unit performs rigid alignment, either selecting globally align that orients the two DICOM volumes based on the known relative orientation difference between the two or specify landmarks to register images rigidly. The online unit then elastically warps the image to register on the incoming image from the offline unit.

The registered image volume is displayed on the incoming offline image frame of reference. Also overlaid on the incoming offline and registered image volumes annotating the suspected lesion boundaries. The two volumes are displayed side-by-side in a locked view. Rotation, slicing, panning, or zooming one of the volumes has the same effect on the other enabling visualization of similar features in both volumes simultaneously.

Plan targets on the volumes by selecting suitable locations within the suspected areas of interest boundary. When sufficient targets have been added, exiting fusion mode imports all targets planned in the offline frame of reference back to the original reconstructed ultrasound volume. This is done based on the deformation field that was estimated from registration (rigid followed by elastic registration).

Substantial Equivalence:

Manufacturer	**Eigen**	**ADAC Laboratories**	**Convergent Imaging Solutions**	**Sentinelle Medical Inc.**	**Traxtal Technologies Inc.**
Product Name	**Multi-Modality Image Fusion**	**Syntegra**	**UniSyn**	**Aegis Navigation**	**Abaris**
510(k) number	pending	K041182	K081987	K093672	K053610
Intended Use	Multi-Modality Image Fusion is a software application used by	Syntegra is a software application for multi-modality	UniSyn is a software application for image	This device provides two and three-dimensional image review,	ABARIS is a stereotaxic accessory for Computed

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	physicians in the clinic or hospital for 2-D and 3-D visualization, multi-modality image registration, and fusion of medical images. Additional software features include database management, communication, surface rendering, segmentation, ROI delineation, measurements, and reporting.	image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals	registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image	manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices. This device is intended to assist skilled medical professionals in clinical screening and	Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. it displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device. The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for

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				interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.	visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.
Where Used	Office settings in clinic or hospital	Office settings in clinic or hospital	Office settings in clinic or hospital	Not specified	clinical interventions
Software Device	Yes	Yes	Yes	Yes	Yes
Image Registratio n	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration	Yes
Image Fusion /Overlay Display	Fused overlay of images from multiple modalities	Fused overlay of images from multiple modalities	Fusion overlay of images from multiple modalities	overlay of images from multiple modalities	Yes
Opacity Control	Yes	Yes	Yes	Not Specified	Not Specified
3-D Rendering	Yes	Yes	Yes	Yes	Yes
Surface Rendering	Yes	Yes	Yes	Yes	Yes
Regions of interest	Yes	Yes	Yes	Yes	Yes
Configura	Yes	Yes	Yes	Yes	Yes

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ble image layouts					
3D Contouring	Yes	Not Specified	Yes	Yes	Yes
Export of 3D contours for planning	Yes	Not Specified	Yes	Not Specified	Yes
Image Storage and Communication	DICOM, JPEG	DICOM (check)	DICOM	DICOM	DICOM
Modalities	CT, MRI, Ultrasound	Positron Emission Tomography (PET) and X-ray Computed Tomography (CT).	CT, PET, SPECT and MR scanners	MRI, US, SPECT, CT, PET, Fluoroscopy, Endoscopy and others	Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems

The product's technical features are substantially equivalent to Syntegra (K041182), UniSyn (K081987), Aegis Navigation (K093672) and Abaris (K053610). The Multi-Modality Image Fusion is a software product that runs on PC-based workstations. Image data is input to the devices and used to generate 3-D views and perform image processing. Like the four predicate devices, the software has image measurement, multi-planar reformatting, segmentation and image registration abilities, fusion of images from different modalities, image storage and retrieval, as well as patient information management functions.

The Syntegra and UniSyn are software products that accept multiple image data types including magnetic resonance, and computed tomography. Aegis Navigation and Abaris are systems that accept multiple modalities that include magnetic resonance, computed tomography and ultrasound. The Multi-Modality Image Fusion has been designed for processing medical images in standard DICOM format. The system is composed of two modules: an offline and an online module for image fusion for planning a procedure.

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Testing and Performance Data:

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were developed and were used to verify system performance.

The device has been designed and manufactured to conform to the following standards:

ACRINEMA PS3.1-3.18 Digital Imaging and Communications in Medicine (DICOM)

ISO 14971 Application of Risk Management to Medical Devices

ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

The following tests were performed:

MMIF Hardware verification Test Procedure

MMIF Online Verification Test Procedure

MMIF Offline Software Application Verification Test Procedure

MMIF Risk Mitigation Verification Test Procedure

Registration Accuracy for Clinical Data (bench test)

Phantom Volume Measurements (bench test)

Phantom Registration Accuracy (bench test)

All the above mentioned tests passed. Theses testing activities were conducted to establish the performance, safety, effectiveness, functionality usability, and reliability characteristics of the new device.

The purpose of the performance testing (bench testing) was to ensure the performance of the new MMIF software by verifying the accuracy of the specifications and simulating real customer data collected from the hospital setting.

The conducted verification tests have confirmed static and dynamic performance of the complete system consisting of both the online and off line software installed on specified hardware. Furthermore these tests establish compliance to the specification under conditions simulation real environment of use.

Conclusion:

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of the Multi-Modality Image Fusion with those of the two predicate devices demonstrate that the Multi-Modality Image Fusion is substantially

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equivalent to existing products on the market today.

The verification and validation testing included bench performance tests, functionality tests, and system test. All tests were successfully completed.

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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

IGT LCC dba Eigen
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street NW
BUFFALO MN 55313

APR - 6 2012

Re: K120187
Trade/Device Name: Multi-Modality Image Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications System
Regulatory Class: II
Product Code: LLZ
Dated: March 1, 2012
Received: March 2 2012

Dear Mr. Job:

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

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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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Form

510(k) Number (if known):

Device Name: Multi-Modality Image Fusion

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) K120187

Page 1 of 1

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Division Sign-Off
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Evaluation and Safety

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 02, 2012

IGT LLC DBA EIGEN
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
ATTN: MARK JOB

510k Number: K120187

Product: MULTI-MODALITY IMAGE FUSION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mcdonald, Lisa *

From: Microsoft Outlook
To: 'mark@markjob.com'
Sent: Friday, March 02, 2012 11:59 AM
Subject: Relayed: K120187 AI Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mark@markjob.com'

Subject: K120187 AI Letter

Sent by Microsoft Exchange Server 2007

8

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 15, 2012

IGT LLC DBA EIGEN
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
ATTN: MARK JOB

510k Number: K120187
Product: MULTI-MODALITY IMAGE FUSION
On Hold As of 2/14/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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To: 'mark@markjob.com'
nt: Wednesday, February 15, 2012 8:30 AM
ubject: Relayed: K120187 Hold Letter

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Public Health Service

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January 23, 2012

IGT LLC DBA EIGEN
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BUFFALO, MINNESOTA 55313
ATTN: MARK JOB

510k Number: K120187

Received: 1/23/2012

Product: MULTI-MODALITY IMAGE FUSION

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

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Grayson, Giovanna *

From: Microsoft Outlook
To: 'mark@markjob.com'
Sent: Monday, January 23, 2012 1:39 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mark@markjob.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

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Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, January 23, 2012 1:39 PM
To: 'mark@markjob.com'
Subject: ack letter
Attachments: image002.png

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Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 23, 2012
MANDEL
WILLIAM
JOB
MARK
IGT LLC DBA EIGEN
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
ATTN: MARK JOB

510k Number: K120187
Received: 1/23/2012
Product: MULTI-MODALITY IMAGE FUSION

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Sincerely,

510(k) Staff

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K120187
RA / DRAD

FDA CDRH DMC
JAN 23 2012
Received

Date: January 20, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

C. Name and Address of the Manufacturer:

IGT LLC dba Eigen

13366 Grass Valley Avenue

Grass Valley, CA 95945

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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D. Device Name

Trade or Proprietary Name: Multi-Modality Image Fusion

Classification Name: Picture Archiving and Communication System

Regulation Number: 21 CFR 892.2050

Recommendation: Substantially Equivalent

Date Submission was received by
Regulatory Technology Services LLC: October 28, 2011

We have enclosed the following materials:

E. Authorization Letter from the applicant (MAL-F-0006).
F. Complete 510(k) application submitted by the applicant.
G. Documented review of the 510(k) application (RPP-F-0012, RPP-F-14 and all correspondence and documents related to the review).
H. Conflict of Interest Certification (RPP-F-0018)
I. Certification (RPP-F-0020)

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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innovation by eigen

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

9 Jan 2011

Reference: Record of Deficiencies From Substantive Review
Device Name or Model Name: Multi-modality Image Fusion
Dated: November 21, 2011

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

www.eigen.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IGT, LLC dba Eigen

13366 Grass Valley Avenue, Grass Valley, CA 95945

Phone 530-274-1240

FAX 530-274-3656

Multi-Modality Image Fusion

William Mandel
Eigen

13366 Grass Valley Avenue, Grass Valley CA 95945

Phone 530-274-1240 x237

FAX 530-274-3656

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 1

Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Form

510(k) Number (if known): pending_____

Device Name: Multi-Modality Image Fusion_____

Indications for Use: Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

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

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

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

_____
Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k)_____

Page 1 of __1_

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Section 3

510(k) Summary

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510(k) Summary

Submitter's Name: IGT, LLC dba Eigen
Submitter's Address: 13366 Grass Valley Avenue, Grass Valley, CA 95945
Submitter's Telephone: 530-274-1240
Contact Name: William Mandel

Date Summary was Prepared: 21 Oct 2011
Trade or Proprietary Name: Multi-Modality Image Fusion
Common or Usual Name: Multi-Modality Image Fusion
Classification Name: System, Image Processing, Radiological, LLZ
Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
Syntegra	K041182
UniSyn	K081987

Intended Use

Indications for Use: Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

Description of the Device and Summary of the Technological Characteristics:

Multi-Modality Image Fusion (MMIF) is software, which comprises of two software components, which is referred to as offline and online. The offline component pertains to the preparation of gland and suspected lesion boundaries on a DICOM image file days or hours prior to the biopsy procedure. The online component fuses the DICOM image files, which were, prepared on the offline component, with a snap shot incoming TRUS image. Each of the two software components can work together or independently.

Offline Software

The offline software can delineate suspected areas of interest using visualization and save this data in a standard format, e.g. as a surface mesh in VTK or STL format. Furthermore, the offline software can optionally delineate the gland boundary from a DICOM image, or other volumes where the boundary can be easily observed. This addition data is also saved in a

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standard format, e.g. surface mesh in VTK or STL or as a binary volume. This software would be typically executed by Radiologists.

Online Software

The online unit software is designed to fuse two images by entering a fusion mode and load the DICOM image and the boundary data provided by the offline unit. The online unit performs rigid alignment, either selecting globally align that orients the two DICOM volumes based on the known relative orientation difference between the two or specify landmarks to register images rigidly. The online unit then elastically warps the image to register on the incoming image from the offline unit.

The registered image volume is displayed on the incoming offline image frame of reference. Also overlaid on the incoming offline and registered image volumes annotating the suspected lesion boundaries. The two volumes are displayed side-by-side in a locked view. Rotation, slicing, panning, or zooming one of the volumes has the same effect on the other enabling visualization of similar features in both volumes simultaneously.

Plan targets on the volumes by selecting suitable locations within the suspected areas of interest boundary. When sufficient targets have been added, exiting fusion mode imports all targets planned in the offline frame of reference back to the original reconstructed ultrasound volume. This is done based on the deformation field that was estimated from registration (rigid followed by elastic registration).

Substantial Equivalence:

Manufacturer	**Eigen**	**ADAC Laboratories**	**Convergent Imaging Solutions**
Product Name	**Multi-Modality Image Fusion**	**Syntegra**	**UniSyn**
510(k) number	pending	K041182	K081987
Intended Use	Indications for Use: Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D	Syntegra is a software application for multi-modality image registration and diagnostic fusion. Images are registered and displayed in a	UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. UniSyn

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	visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.	"fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals	creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image
Where Used	Office settings in clinic or hospital	Office settings in clinic or hospital	Office settings in clinic or hospital
Software Device	Yes	Yes	Yes
Image Registration	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration
Image Fusion Display	Fused overlay of images from multiple modalities	Fused overlay of images from multiple modalities	Fusion overlay of images from multiple modalities
Opacity Control	Yes	Yes	Yes
3-D Rendering	Yes	Yes	Yes
Surface Rendering	Yes	Yes	Yes
Regions of interest	Yes	Yes	Yes
Configurable image layouts	Yes	Yes	Yes
3D Contouring	Yes	--	Yes
Export of 3D contours for planning	Yes	--	Yes
Image Storage and Communication	DICOM, JPEG	DICOM (check)	DICOM

The product's technical features are substantially equivalent to the Syntegra (K041182) and the UniSyn (K081987). The Multi-Modality Image Fusion is a software product that runs on PC-based workstations. Image data is input to the devices and used to generate 3-D views and perform image processing. Like the two predicate devices, the software has image measurement, multi-planar reformatting, segmentation and image registration abilities, fusion

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of images from different modalities, image storage and retrieval, as well as patient information management functions.

The Syntegra and UniSyn are software products that accept multiple image data types including magnetic resonance, computed tomography, and ultrasound. The Multi-Modality Image Fusion has been designed for processing medical images in standard DICOM format. The system is composed of two modules: an offline and an online module for image fusion for planning a procedure.

Testing and Performance Data:

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were developed and were used to verify system performance.

The device has been designed and manufactured to conform to the following standards:

ACRINEMA PS3.1-3.18 Digital Imaging and Communications in Medicine (DICOM)

ISO 14971 Application of Risk Management to Medical Devices

ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

The following tests were performed:

MMIF Hardware verification Test Procedure

MMIF Online Verification Test Procedure

MMIF Offline Software Application Verification Test Procedure

MMIF Risk Mitigation Verification Test Procedure

Registration Accuracy for Clinical Data (bench test)

Phantom Volume Measurements (bench test)

Phantom Registration Accuracy (bench test)

All the above mentioned tests passed. Theses testing activities were conducted to establish the performance, safety, effectiveness, functionality usability, and reliability characteristics of the new device.

The purpose of the performance testing (bench testing) was to ensure the performance of the new MMIF software by verifying the accuracy of the specifications and simulating real customer data collected from the hospital setting.

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The conducted verification tests have confirmed static and dynamic performance of the complete system consisting of both the online and off line software installed on specified hardware. Furthermore these tests establish compliance to the specification under conditions simulating real environment of use.

Conclusion:

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of the Multi-Modality Image Fusion with those of the two predicate devices demonstrate that the Multi-Modality Image Fusion is substantially equivalent to existing products on the market today.

The verification and validation testing included bench performance tests, functionality tests, and system test. All tests were successfully completed.

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Internal Technical Report #: 234-07003-10

Phantom Volume Measurements

Multi-Modality Image Fusion

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Internal Technical Report # 234-07004-10

CT/US Phantom Registration Accuracy

Multi-Modality Image Fusion

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2. Workflow and Method

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3. Results

[redacted]

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Table 1: Eight cases for registration

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4. Conclusions

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Design Controls
Standard Operating Procedure

Document No. 227-00000-00
Rev C

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Product Development Plan

Multi-Modality Image Fusion System

Document No. 233-07001-10
Rev D

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Section 11

Anomaly Impact on Safety or Effectiveness

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11 Anomaly Impact on Safety or Effectiveness

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46	4501	When selecting Dual	Incorrect	It is not unusual to see one

[redacted]

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Multi-Modality Image Fusion

innovation by eigen

User Manual
790-07000-10 Rev C

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Appendix A – Software Licensing

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Image Viewer

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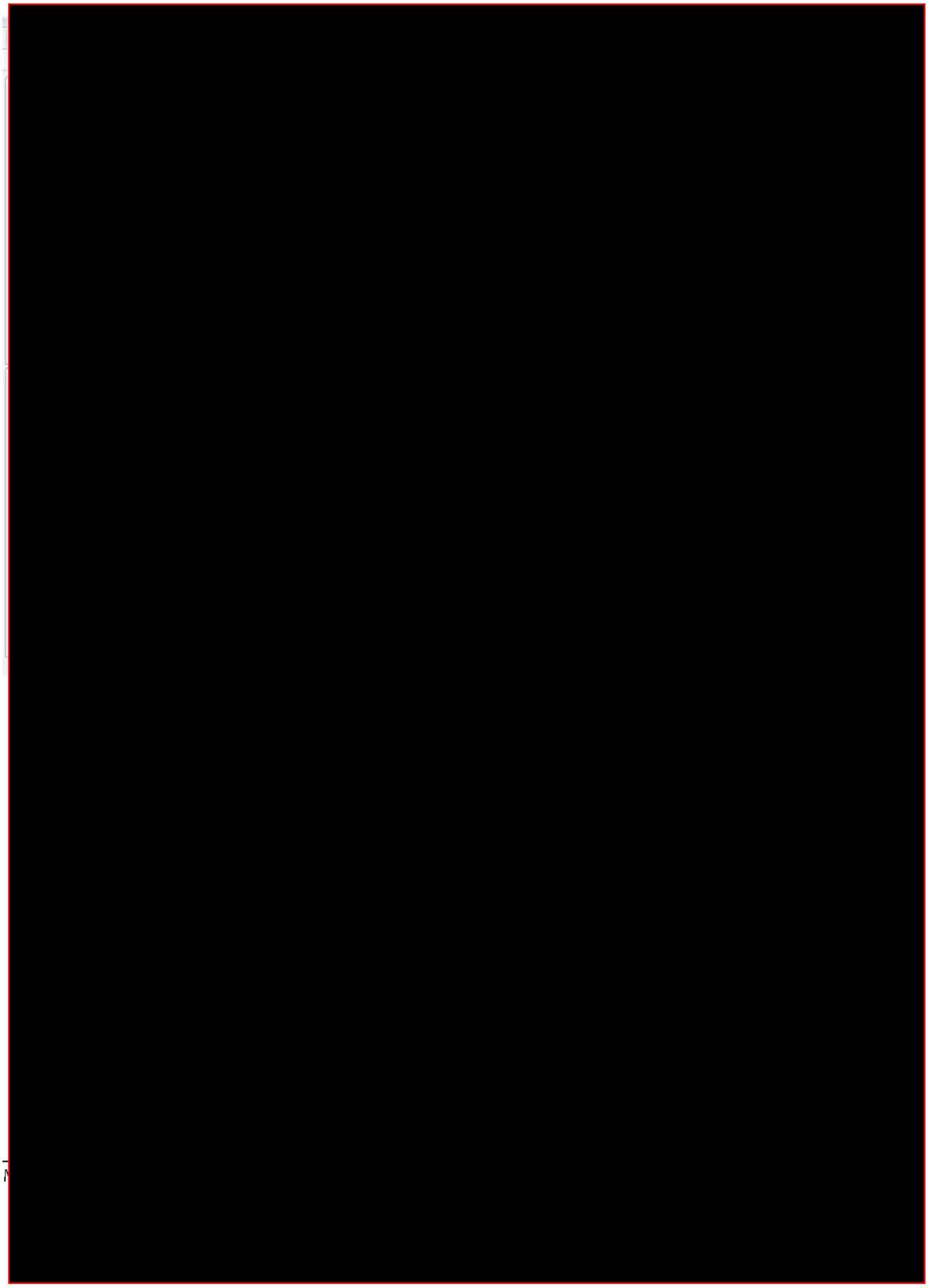

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

NEMA: PS 3.1 - 3.18: Digital Imaging and Communications in Medicine (DICOM) Set: 2009

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-218	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Software Architecture Design - Overview

Multi-Modality Image Fusion

Document No. 233-07015-10

Rev A

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Software Design Specification (ERD)

Multi-Modality Image Fusion

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Engineering Requirements Specification

Multi-Modality Image Fusion

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MMI Fusion Traceability Matrix

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jay Vashnav

Subject: 510(k) Number K120187/S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source? ✓

All Pediatric Patients age<=21 ✓

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology ✓

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.* ✓

Regulation Number	**Class***	**Product Code**
21 CFR 892.2050	II	LLZ

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) (Branch Code) (Date)

Final Review: (Division Director) 4/6/12 (Date)

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U.S. Department of Health and Human Services
Food and Drug Administration

Division of Radiological Devices
Office of In Vitro Diagnostics
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Third Party

K120187/S001

Date:	April 4, 2012	
To:	The Record	Office: OIVD
From:	Jay Y. Vaishnav, Ph.D.	Division: DRAD

510(k) Holder:	Eigen
Device Name:	Multi Modality Image Fusion
Contact:	Mark Job (accredited third party reviewer) Regulatory Technology Services Incorporated 1394 25th Street, NW Buffalo, Minnesota 55313
Phone:	763 682 4139
Fax:	763 682 4420
Email:	mark@markjob.com

I. Purpose and Submission Summary

Eigen, Inc. is submitting a 510(k) to introduce the Multi Modality Image Fusion software into interstate commerce. This submission is a third party submission, and the review is the second review of this submission. The device is a new device.

The device is a software-only device for postprocessing of medical images. The software is a universal DICOM viewer for X-ray, Ultrasound, MR, CT, and nuclear medicine images. It performs 2-D and 3-D visualization as well as multi-modality image registration and fusion. The device operates on various imaging modalities including CT, MR, and US images. The sponsor has provided verification and validation data on the image registration. The sponsor states that the device does not require contrast-enhanced images in order to operate.

The intended use of this device is to assist a user in preparing boundaries on glands and suspected lesions prior to biopsy procedures.

Differences from the Predicate Device:

S000: Although the device performed similar operations to the predicate devices, none of the predicate devices operated on ultrasound images. This was issued as a deficiency.

S001: The sponsor added two predicate devices that operate on ultrasound images.

The software performs similar functions to the predicate devices, although its capabilities are more limited than some of the predicate devices'. One of the predicate devices is a hardware device that includes a software component; the functionality of this device is similar to the software component of that device.

Recommendation: Substantially Equivalent

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

II. Administrative Requirements

	Sufficient	
	Yes	No
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)	✓	
510(k) Cover Letter	✓	
Indications for Use	Rx	
510(k) Summary	✓	
(a) 510(k) Summary is in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence (21 CFR §807.92)	✓	
(1) Submitter's Contact Information	✓	
(2) Device Name	✓	
(3) Predicate Identification	✓	
(4) Device Description	✓	
(5) Intended Use Statement	✓	
(6) Technological Characteristics Comparison	✓	
(b) Performance Data	✓	
(1) Brief Discussion of Nonclinical Tests	✓	
(2) Brief Discussion of Clinical Tests		N/A
(3) Test Conclusions	✓	
Truthful and Accuracy Statement	✓	
Class III Summary		N/A
Financial Certification or Disclosure Statement		N/A
Standards Form (FDA 3654) • NEMA PS3.1-3.18 (DICOM) • ISO 14971 – Application of Risk Management to Medical Devices • ISO 13485 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	✓	
Clinical Trials Form (FDA 3674)		N/A

III. Indications for Use

The IFU statements of subject and predicate devices are below:

Predicate Device	Predicate Device	Predicate Device	Predicate Device	Subject Device
K041182, Syntegra (ADAC Laboratories)	K081987, UniSyn (Convergent Imaging Solutions)	K093672, Aegis Navigation (Sentinelle Medical Inc.)	K053610, Abaris (Traxtal Technologies, Inc.)	K120187, MultiModality Image Fusion (Eigen)

LLZ (21 CFR §892.2050)	LLZ (21 CFR §892.2050)	LLZ (21 CFR §892.2050)	IYO, JAK (21 CFR 892.1750)	LLZ (21 CFR §892.2050)
Syntegra is a software application for multi-modality image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals	UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image	This device provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other	ABARIS is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. It displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the	Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

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		tracked devices. This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.	interventional device is displayed relative to another device. The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.	

The following differences exist between the subject and predicate device indications:

- The subject device includes indications for ultrasound visualization. The predicates do not appear to operate on ultrasound images.

  A deficiency was issued in S000. The image modalities that the device operated on were different from those that the predicate devices operated on. In particular, the subject device operated on ultrasound images. In S001, the sponsor has added two additional predicate devices that operate on ultrasound images. The additional predicates perform

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the same image processing functions as part of more extensive functionality. The lead reviewer considers the deficiency closed.

- The subject device includes indications for communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

  This is not an issue since the predicate devices do have these intended uses, although they are not present in the respective IFU statements.

IV. Device Description

Component	Material(s)	Attributes	Acceptable	
			Yes	No
Software	Software	Reusable ~~Patient contact~~ ~~Implant~~ ~~Biocompatibility Testing~~ ~~Sterilization~~ ~~Cleaning Instructions~~ ~~Electrical/Magnetic/Thermal Compatibility~~ ~~Imaging Contrast Required~~ ~~Life-Supporting or Life-Sustaining~~	✓	
The device is software only. The device operates on contrast-enhanced CT images.				

The device is a software-only device designed for the postprocessing of a variety of image modalities including CT and MR.

The software can be loaded on a standard PC and can operate as a stand-alone or server configuration.

The software does not require the use of contrast-enhanced images.

The software can be used to annotate, measure, and output selected image views or reports.

V. Predicate Device Comparison

Manufacturer	Eigen	ADAC Laboratories	Convergent Imaging Solutions	Sentinelle Medical Inc.	Traxtal Technologies Ihc.
Product Name	Multi-Modality Image Fusion	Syntegra	UniSyn	Aegis Navigation	Abaris
510(k) number	pending	K041182	K081987	K093672	K053610
Software Device	Yes	Yes	Yes	Yes	Yes
Image Storage and Communication	DICOM, JPEG	DICOM	DICOM	DICOM	DICOM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Modalities	CT, MR, US	PET, CT	PET, CT, SPECT, MR	MRI, US, SPECT, CT, PET, Fluoroscopy, Endoscopy and others	CT, MR, PET, SPECT, Fluoroscopy, Endoscopy and others

All five devices perform image measurement, multi-planar reformatting, segmentation, and image registration.

S000: The primary difference between the devices appears to be the modality of images on which they operate. Although the sponsor claims (p. 3 of their 510(k) summary) that the predicates operate on ultrasound images, I was not able to verify this. **Please see Section XVI of this memorandum for the original deficiencies that were issued.**

S001: The predicates did not operate on ultrasound images. The sponsor has added two predicate devices that do. The intended uses of these predicate devices expand over the subject devices; however the subject device does appear to replicate a subset of their functionality. The lead reviewer believes that adding the other predicates does address the deficiency. Please see Section XVI of this memorandum.

VI. Labeling

	Sufficient	
	Yes	No
Manufacturer's Contact Information	✓	
Prescription use statement	✓	
Intended Use / Indications for Use	✓	
Relevant notes, cautions, warnings, and/or contraindications	✓	
Symbols *(with description)*		N/A
Device Description	✓	
Hardware Requirements (for software)	✓	
Accessories		N/A
Directions for Use	✓	
Performance Specifications		N/A
Description of quality assurance tests (and action limits)		N/A
Marketing brochures/flyers/claims		N/A

IX. Software

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	Location	Sufficient	
		Yes	No
Level of Concern: The sponsor correctly identifies the software's level of concern as "Moderate." A malfunction or a latent design flaw in the software device could lead to erroneous diagnosis or a delay in delivery of appropriate medical care.	p. 16-2	✓	
Software Description: The sponsor provided an acceptable description of the device.	p. 16-3	✓	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	Location	Sufficient	
		Yes	No
Device Hazard Analysis: The sponsor provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards.	p. 16-50	✓	
Software Requirements Specifications: The sponsor provided an SRS documenting the functional, performance, interface, design and development requirements in an enumerated fashion.	AI	✓	
Architecture Design Chart: The sponsor provided an acceptable description of the software system partitioned into its functional subsystems.	AI	✓	
Design Specifications: The sponsor provided an SDS describing how the requirements in the Software Requirements Specifications (SRS) were implemented.	AI	✓	
Traceability Analysis/Matrix: The sponsor provided a traceability analysis/matrix to show that individual hazards and requirements had been linked with verification/validation testing.	AI	✓	
Development Environment: The sponsor provided a sufficient description of their software development process.	AI	✓	
Verification & Validation Testing: The sponsor provided a description of validation and verification activities at the unit, integration, and system level. This description included the unit, integration and system level test protocols, including pass/fail criteria, test reports, summary and test results. The sponsor provided a description of tests that were not passed, modifications made in response to failed tests and documentation demonstrating that said modifications were effective.	Appendix D	✓	
Revision Level History: The sponsor provided the revision history log, documenting all major changes to the software during its development cycle.	Appendix G	✓	
Unresolved Anomalies: The sponsor states that no anomalies remain unresolved.	AI	✓	

The sponsor has included a DICOM conformance statement (Section 9).

XI. Performance Testing – Bench/Animal/Clinical

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Bench Testing

The sponsor performed verification and validation testing on the software.

The testing includes phantom testing to validate MR-US and CT-US registration.

The sponsor has performed four sets of testing. This testing includes volume estimation and phantom registration for both MR-US and CT-US images. The sponsor quotes results that fall within their prespecified accuracy criteria.

Testing on Clinical Images

The sponsor has provided performance test results using a known data set from Sheba Medical Center, Department of Radiology, Israel. The images selected intentionally included significant findings in order to challenge the Hounsfield unit algorithm. The analysis included 100 pre-read cases. The clinical cases were read in the normal clinical process at Sheba Medical Center by qualified staff radiologists. The results were reviewed by both the system development test group and a radiologist.

XV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indications for Use statement?	✓		If **YES** = Go To 3
2. Do differences alter the effect or raise new issues of safety or effectiveness?		✓	If **YES** = Stop **NSE**
3. Same technological characteristics?	✓		If **YES** = Go To 5
4. Could the new characteristics affect safety or effectiveness?			If **YES** = Go To 6
5. Descriptive characteristics precise enough?		✓	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New types of safety or effectiveness questions?			If **YES** = Stop **NSE**
7. Accepted scientific methods exist?			If **NO** = Stop **NSE**
8. Performance data available?	✓		If **NO** = Request Data
9. Data demonstrate equivalence?	✓		Final Decision: **SE**

1. Explain how the new indication differs from the predicate device's indication:
The subject device registers ultrasound images with CT and MR images. It is not clear whether the predicates operate on ultrasound images.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
Many software devices do operate on US images, and the sponsor has validated the device's performance. The primary function of this device appears to be registering images. There is no reason that ultrasound images cannot be correctly registered.

3. Describe the new technological characteristics: N/A

4. Explain how the new characteristics could or could not affect safety or effectiveness: N/A

5. Explain how descriptive characteristics are not precise enough:

This device is a software device. The sponsor should therefore submit verification and validation in addition to descriptive information about the device.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: N/A

7. Explain why existing scientific methods can not be used: N/A

8. Explain what performance data is needed:
N/A

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The sponsor has provided bench data validating that the device can correctly register images from different modalities within pre-specified tolerances.

XVI. Previous Deficiencies

In addition to deficiencies identified by Mr. Job, I have identified the following deficiencies. I am communicating the deficiencies to Mr. Job via e-mail (2/9/12):

1. The device has a different IFU statement than either of the predicate devices. However, the flowchart you have provided in your review memorandum states that the device has the same IFU statement. Please provide a corrected flowchart.

S001: The third party reviewer has corrected the flowchart. The deficiency is closed.

2. The subject device is indicated to operate on a variety of images, including ultrasound images. Although the 510(k) summary of the subject device states that the predicate devices operate on MR, CT, and ultrasound images, we were not able to establish that either of the predicate devices operates on ultrasound images. Predicate K081987 operates on CT, PET, SPECT, and MR images, and predicate K041182 appears to perform PET/CT registration. Please direct us to labeling demonstrating that the predicate devices operate on ultrasound images. Furthermore, please expand your substantial equivalence discussion to clarify what image modalities each device operates on.

S001: The sponsor has corrected the submission. The two predicates originally identified did not operate on ultrasound images, although the image processing algorithms were similar. The sponsor has added two more predicates that do operate on ultrasound images. The lead reviewer believes that the additional information that the sponsor has provided is sufficient to close the deficiency.

3. The subject device operates on CT images. Please clarify which functions of the device require contrast-enhanced images to operate, and whether these functions are also present in the predicate device.

S001: The sponsor has clarified that the device does not operate on contrast-enhanced images. The deficiency is closed.

4. The IFU statement suggests that the device is for general use by "physicians." However p. 1-1 of the manual suggests that the device is for use by "urologists." Please clarify the intended use of the device.

The sponsor has modified the user manual appropriately.

XVII. Outstanding Deficiencies

The deficiencies issued by the third party have been resolved.
The deficiencies identified in S001 have been resolved.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The lead reviewer did not identify further deficiencies.

XVIIII. Recommendation: Substantially Equivalent
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ

J. J. Vaishnav

Jay Vaishnav, PhD — April 4, 2012 Date

Supervisor — 4/6/2012 Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jay Vaishnav

Subject: 510(k) Number K120187

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*		✓
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?		✓	
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			

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leonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number 21 CFR 892.2050

Class* II

(*If unclassified, see 510(k) Staff)

Product Code LLZ

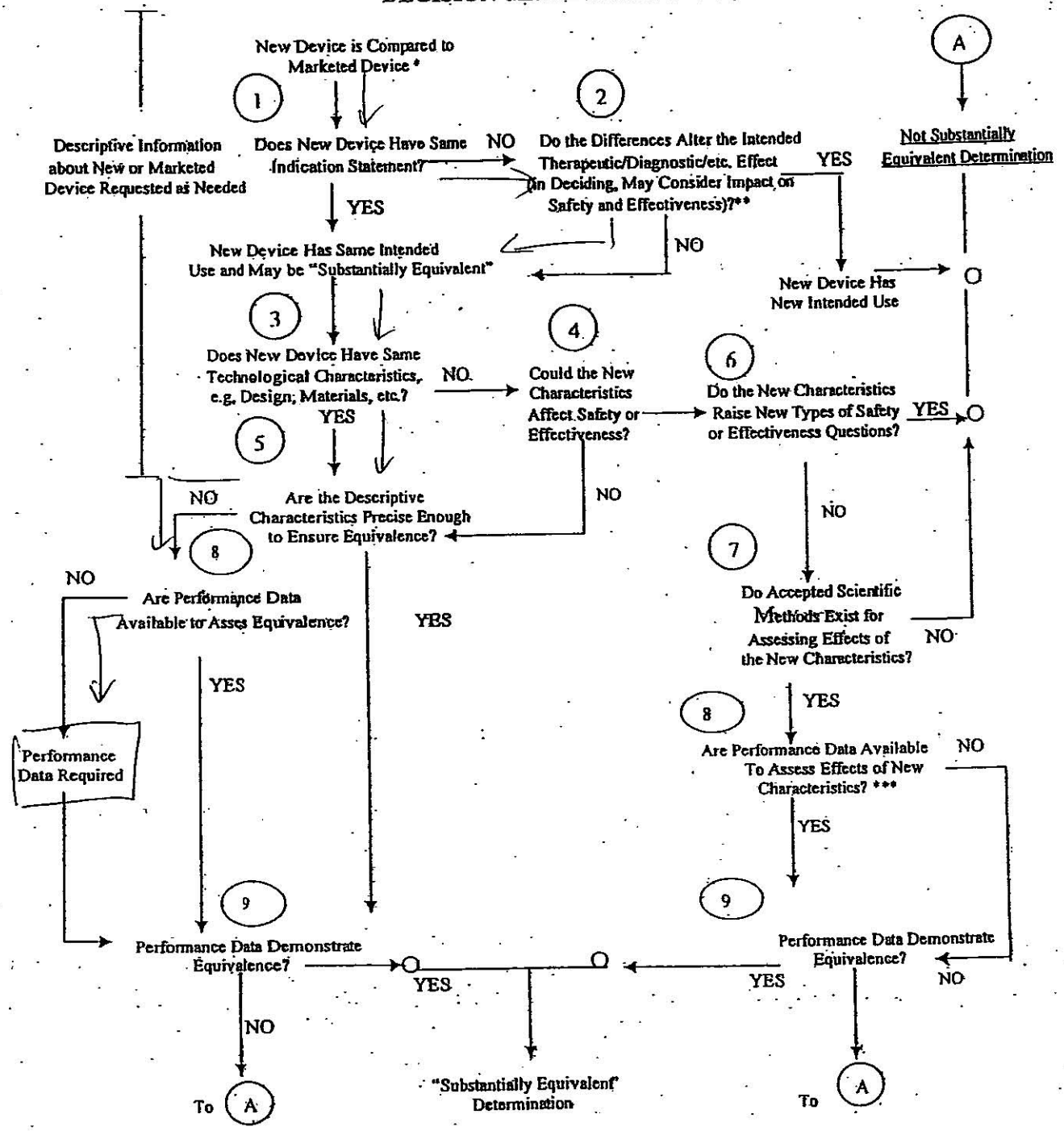
Additional Product Codes:

Review: [signature] (Branch Chief) DRAD (Branch Code) 2/14/2012 (Date)

Final Review: (Division Director) (Date)

Records processed under FOIA Request 2012-4643; Released 1/13/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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THIRD PARTY REVIEW CHECKLIST

Is this 510(k) eligible for third party review?	Yes	No
Is the device on the list of eligible devices?* †	✓	
Can a determination of substantial equivalence be made without clinical data?†	✓	
Are you aware of the 510(k) holder being the subject of an Integrity Investigation? ‡		✓

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring file to POS.
† If no, please bring submission to POS immediately.
‡ If yes, please bring submission to POS immediately.

A cover letter signed by the third party's official correspondent clearly identifying:	Yes	No
The purpose of the submission	✓	
The name and address of the third party	✓	
The name and address of the 510(k) holder	✓	
The purpose of the submission	✓	
The name of the device (trade name, common or usual name, and FDA classification name)	✓	
The third party's recommendation with respect to the substantial equivalence of the device	✓	
The date the third party first received the 510(k) from the 510(k) holder	✓	
A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	✓	
The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	✓	
A complete review of the 510(k) signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	✓	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

A certification that:	Yes	No
The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	✓	
Statements made in the third party's review are true and accurate to the best knowledge of the third party	✓	
The third party's review is based on the 510(k) that it is submitting with the review	✓	
The third party understands that the submission to the government of false information is prohibited	✓	
Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:		
Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	✓	
Record of Deficiencies, if applicable	✓	
Indications for Use Form	✓	
510(k) Summary or Statement	✓	
510(k) Truthful and Accurate Statement	✓	
Third Party "Substantial Equivalence" (SE) Decision Making Documentation	✓	

If any of the above information is not included with the third party submission or is not adequate contact the third party and attempt to resolve the deficiency. Please include a memorandum to the record of the telephone call. When the information is received please revise this checklist or complete a new one.

COMMENTS:

Records processed under FOIA Request 2012-4643; Released 1/13/14

U.S. Department of Health and Human Services
Food and Drug Administration

Division of Radiological Devices
Office of In Vitro Diagnostics
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Third Party

K120187

Date:	February 13, 2012	
To:	The Record	Office: OIVD
From:	Jay Y. Vaishnav, Ph.D.	Division: DRAD

510(k) Holder:	Eigen
Device Name:	Multi Modality Image Fusion
Contact:	Mark Job (accredited third party reviewer) Regulatory Technology Services Incorporated 1394 25th Street, NW Buffalo, Minnesota 55313
Phone:	763 682 4139
Fax:	763 682 4420
Email:	mark@markjob.com

I. Purpose and Submission Summary

Eigen, Inc. is submitting a 510(k) to introduce the Multi Modality Image Fusion software into interstate commerce. This submission is a third party submission, and the review is the first review of this submission. The device is a new device.

The device is a software-only device for postprocessing of medical images. The software performs 2-D and 3-D visualization as well as multi-modality image registration and fusion. The device operates on various imaging modalities including CT, MR, and US images.

Recommendation: Telephone hold

II. Administrative Requirements

	Sufficient	
	Yes	No
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)	✓	
510(k) Cover Letter	✓	
Indications for Use	Rx	
510(k) Summary	✓	
(a) 510(k) Summary is in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence (21 CFR §807.92)	✓	
(1) Submitter's Contact Information	✓	
(2) Device Name	✓	
(3) Predicate Identification	✓	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Sufficient	
	Yes	No
(4) Device Description	✓	
(5) Intended Use Statement	✓	
(6) Technological Characteristics Comparison	✓	
(b) Performance Data	✓	
(1) Brief Discussion of Nonclinical Tests	✓	
(2) Brief Discussion of Clinical Tests		N/A
(3) Test Conclusions	✓	
Truthful and Accuracy Statement	✓	
Class III Summary		N/A
Financial Certification or Disclosure Statement		N/A
Standards Form (FDA 3654) • NEMA PS3.1-3.18 (DICOM) • ISO 14971 – Application of Risk Management to Medical Devices • ISO 13485 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	✓	
Clinical Trials Form (FDA 3674)		N/A

III. Indications for Use

The IFU statements of subject and predicate devices are below:

Predicate Device K041182, Syntegra (ADAC Laboratories) LLZ (21 CFR §892.2050)	**Predicate Device** K081987, UniSyn (Convergent Imaging Solutions) LLZ (21 CFR §892.2050)	**Subject Device** K120187, MultiModality Image Fusion (MeVis Medical Solutions) LLZ (21 CFR §892.2050)
Syntegra is a software application for multi-modality image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals	UniSyn is a software application for image registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image	Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

The following differences exist between the subject and predicate device indications:

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- The subject device includes indications for ultrasound visualization.

  Please see Section XVI of this memorandum for deficiencies.

- The subject device includes indications for communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

  This is not an issue since the predicate devices do have these intended uses, although they are not present in the IFU statement.

IV. Device Description

Component	Material(s)	Attributes	Acceptable	
			Yes	No
Software	Software	Reusable ~~Patient contact~~ ~~Implant~~ ~~Biocompatibility Testing~~ ~~Sterilization~~ ~~Cleaning Instructions~~ ~~Electrical/Magnetic/Thermal Compatibility~~ Imaging Contrast Required ~~Life-Supporting or Life Sustaining~~	✓	
The device is software only. The device operates on contrast-enhanced CT images.				

The device is a software-only device designed for the postprocessing of a variety of image modalities including CT and MR.

The software can be loaded on a standard PC and can operate as a stand-alone or server configuration.

The software can be used to annotate, measure, and output selected image views or reports.

V. Predicate Device Comparison

Category	Predicate Device K041182, Syntegra (ADAC Laboratories) LLZ (21 CFR §892.2050)	Predicate Device K081987, UniSyn (Convergent Imaging Solutions) LLZ (21 CFR §892.2050)	Subject Device K120187, MultiModality Image Fusion (MeVis Medical Solutions) LLZ (21 CFR §892.2050)
PACS	Yes		
Image modalities	CT, PET, SPECT	CT, MRI	CT, MRI, **US**
Compression	DICOM	DICOM	DICOM, **JPG**
Intended Use	Image registration and fused overlay of multi-modality images		
Hardware	Commercial PC		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

All three devices perform image measurement, multi-planar reformatting, segmentation, and image registration. The primary difference between the devices seems to be the modality of images on which they operate. Although the sponsor claims (p. 3 of their 510(k) summary) that the predicates operate on ultrasound images, I was not able to verify this. **Please see Section XVI of this memorandum for deficiencies.**

VI. Labeling

	Sufficient	
	Yes	No
Manufacturer's Contact Information	✓	
Prescription use statement	✓	
Intended Use / Indications for Use	✓	
Relevant notes, cautions, warnings, and/or contraindications	✓	
Symbols *(with description)*		N/A
Device Description	✓	
Hardware Requirements (for software)	✓	
Accessories		N/A
Directions for Use	✓	
Performance Specifications		N/A
Description of quality assurance tests (and action limits)		N/A
Marketing brochures/flyers/claims		N/A

IX. Software

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	Location	Sufficient	
		Yes	No
Level of Concern: The sponsor correctly identifies the software's level of concern as "Moderate." A malfunction or a latent design flaw in the software device could lead to erroneous diagnosis or a delay in delivery of appropriate medical care.	p. 16-2	✓	
Software Description: The sponsor provided an acceptable description of the device.	p. 16-3	✓	
Device Hazard Analysis: The sponsor provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards.	p. 16-50	✓	
Software Requirements Specifications: The sponsor provided an SRS documenting the functional, performance, interface, design and development requirements in an enumerated fashion.	AI	✓	
Architecture Design Chart: The sponsor provided an acceptable description of the software system partitioned into its functional subsystems.	AI	✓	
Design Specifications: The sponsor provided an SDS describing how the requirements in the Software Requirements Specifications (SRS) were implemented.	AI	✓	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	Location	Sufficient	
		Yes	No
Traceability Analysis/Matrix: The sponsor provided a traceability analysis/matrix to show that individual hazards and requirements had been linked with verification/validation testing.	AI	✓	
Development Environment: The sponsor provided a sufficient description of their software development process.	AI	✓	
Verification & Validation Testing: The sponsor provided a description of validation and verification activities at the unit, integration, and system level. This description included the unit, integration and system level test protocols, including pass/fail criteria, test reports, summary and test results. The sponsor provided a description of tests that were not passed, modifications made in response to failed tests and documentation demonstrating that said modifications were effective.	Appendix D	✓	
Revision Level History: The sponsor provided the revision history log, documenting all major changes to the software during its development cycle.	Appendix G	✓	
Unresolved Anomalies: The sponsor states that no anomalies remain unresolved.	AI	✓	

The sponsor has included a DICOM conformance statement (Section 9).

XI. Performance Testing – Bench/Animal/Clinical

Bench Testing

The sponsor performed verification and validation testing on the software.

The testing includes phantom testing to validate MR-US and CT-US registration.

The sponsor has performed four sets of testing. This testing includes volume estimation and phantom registration for both MR-US and CT-US images. The sponsor quotes results that fall within their prespecified accuracy criteria.

Testing on Clinical Images

The sponsor has provided performance test results using a known data set from Sheba Medical Center, Department of Radiology, Israel. The images selected intentionally included significant findings in order to challenge the Hounsfield unit algorithm. The analysis included 100 pre-read cases. The clinical cases were read in the normal clinical process at Sheba Medical Center by qualified staff radiologists. The results were reviewed by both the system development test group and a radiologist.

XV. Substantial Equivalence Discussion

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Yes	No	
1. Same Indications for Use statement?	✓		If **YES** = Go To 3
2. Do differences alter the effect or raise new issues of safety or effectiveness?		✓	If **YES** = Stop **NSE**
3. Same technological characteristics?	✓		If **YES** = Go To 5
4. Could the new characteristics affect safety or effectiveness?			If **YES** = Go To 6
5. Descriptive characteristics precise enough?		✓	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New types of safety or effectiveness questions?			If **YES** = Stop **NSE**
7. Accepted scientific methods exist?			If **NO** = Stop **NSE**
8. Performance data available?		✓	If **NO** = Request Data
9. Data demonstrate equivalence?			Final Decision: **SE**

1. Explain how the new indication differs from the predicate device's indication:
The subject device registers ultrasound images with CT and MR images. It is not clear whether the predicates operate on ultrasound images.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
Many PACS devices do operate on US images, and the sponsor has validated the device's performance.

3. Describe the new technological characteristics: N/A

4. Explain how the new characteristics could or could not affect safety or effectiveness: N/A

5. Explain how descriptive characteristics are not precise enough:
The sponsor should clarify the substantial equivalence of their device to the predicate devices.
Please see Section XVI of this memorandum for deficiencies.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: N/A

7. Explain why existing scientific methods can not be used: N/A

8. Explain what performance data is needed:
Please see Section XVI of this memorandum for deficiencies.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: N/A

XVI. Deficiencies

In addition to deficiencies identified by Mr. Job, I have identified the following deficiencies. I am communicating the deficiencies to Mr. Job via e-mail (2/9/12):

1. The device has a different IFU statement than either of the predicate devices. However, the flowchart you have provided in your review memorandum states that the device has the same IFU statement. Please provide a corrected flowchart.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

2. The subject device is indicated to operate on a variety of images, including ultrasound images. Although the 510(k) summary of the subject device states that the predicate devices operate on MR, CT, and ultrasound images, we were not able to establish that either of the predicate devices operates on ultrasound images. Predicate K081987 operates on CT, PET, SPECT, and MR images, and predicate K041182 appears to perform PET/CT registration. Please direct us to labeling demonstrating that the predicate devices operate on ultrasound images. Furthermore, please expand your substantial equivalence discussion to clarify what image modalities each device operates on.

3. The subject device operates on CT images. Please clarify which functions of the device require contrast-enhanced images to operate, and whether these functions are are also present in the predicate device.

4. The IFU statement suggests that the device is for general use by "physicians." However p. 1-1 of the manual suggests that the device is for use by "urologists." Please clarify the intended use of the device.

XVIII. Recommendation: Telephone hold

Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ

J. J. Vaishnav

Jay Vaishnav, PhD — February 13, 2012 Date

Supervisor — 2/14/2012 Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

Vaishnav, Jay

From: Vaishnav, Jay
Sent: Monday, February 13, 2012 1:13 PM
To: 'MARK JOB'
Cc: O'Hara, Michael D
Subject: K120187 (Multi Modality Image Fusion software by Eigen) Telephone Hold

Dear Mr. Job:

Thank you for submitting K120187 (the Multi Modality Image Fusion software by Eigen) for consideration under the 510(k) clearance process. As you know, 510(k) clearance requires a finding of substantial equivalence between the submitted device and an appropriate predicate device.

We find that there is not sufficient information in the submission for us to make a clear determination of the equivalence of your device to the designated predicate device. We would therefore appreciate your and the sponsor's providing the following additional information:

1. The device has a different IFU statement than either of the predicate devices. However, the flowchart you have provided in your review memorandum states that the device has the same IFU statement. Please provide a corrected flowchart.

2. The subject device is indicated to operate on a variety of images, including ultrasound images. Although the 510(k) summary of the subject device states that the predicate devices operate on MR, CT, and ultrasound images, we were not able to establish that either of the predicate devices operates on ultrasound images. Predicate K081987 operates on CT, PET, SPECT, and MR images, and predicate K041182 appears to perform PET/CT registration. Please direct us to labeling demonstrating that the predicate devices operate on ultrasound images. Furthermore, please expand your substantial equivalence discussion to clarify what image modalities each device operates on.

3. The subject device operates on CT images. Please clarify which, if any, functions of the device require contrast-enhanced images to operate, and whether these functions are are also present in the predicate device.

4. The IFU statement suggests that the device is for general use by "physicians." However p. 1-1 of the manual suggests that the device is for use by "urologists." Please clarify the intended use of the device.

The requested information is necessary for us to adequately compare the devices and assess the level of equivalence which exists between the submitted device and the designated predicate device. After we have received and assessed the requested information, we may ask additional questions to further clarify the extent of equivalence which exists between the two devices.

Pending our receipt of the requested information, I am recommending that FDA place the submission on Telephone Hold to stop the review clock and provide the sponsor additional time to provide the requested information. Please note that this recommendation does not reflect on either the quality of the submission or on the likely outcome of the review. It merely stops the review clock to ensure that adequate time remains for the review of the information that you provide pursuant to this, or any additional, requests.

Please submit your official response and any additional information you provide to the FDA Document and Mail Center (WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002) within thirty days. Should you require more than thirty days to assemble the requested materials, please submit a request for additional time to the FDA Document and Mail Center.

Should you have any questions about the additional information required, please contact me using the contact information listed below.

Thank you for your attention; I look forward to your prompt response and to continuing my review.

Jay Vaishnav, Ph.D.
Division of Radiological Devices
US Food and Drug Administration
Building 66 Room G322
10903 New Hampshire Avenue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

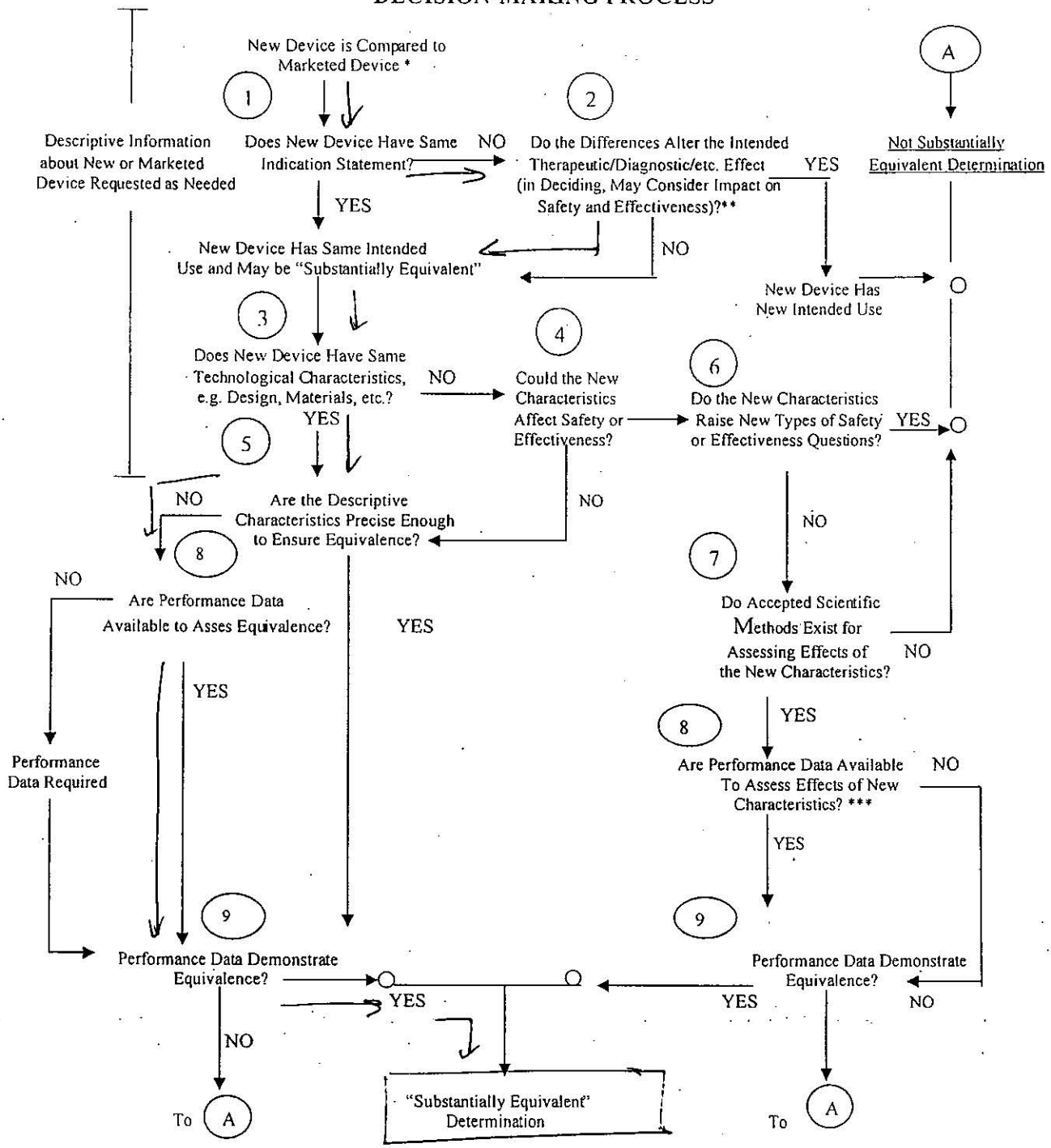
Records processed under FOIA Request 2012-4643; Released 1/13/14

Silver Spring, MD 20993-0002
E-mail: jay.vaishnav@fda.hhs.gov
Phone: (301) 796-9580

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

FDA Cover Letter K120187/S1 RA/DRAD Regulatory Technology Services LLC

FDA CDRH DMC
MAR 02 2012
Received

Date: March 1, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification K120187
IGT LLC dba Eigen
Multi-Modality Image Fusion

To Whom It May Concern:

Enclosed in duplicate is the following information:

As requested by an email received from Jay Vaishnav dated February 13, 2012, requesting additional information for this submission. Based on this review of the additional information, a decision of substantially equivalence is recommended.

If you should have any further questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

innovation by eigen

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

23 Feb 2012

Reference email: K120187 (Multi Modality Image Fusion software by Eigen)
Device Name or Model Name: Multi-modality Image Fusion
Dated: 14 Feb 2012

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

IGT, LLC dba Eigen

13366 Grass Valley Avenue, Grass Valley, CA 95945
Phone 530-274-1240
FAX 530-274-3656

Multi-Modality Image Fusion

William Mandel
Eigen
13366 Grass Valley Avenue, Grass Valley CA 95945
Phone 530-274-1240 x237
FAX 530-274-3656

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2012-4643; Released 1/13/14

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Section 1

510(k) Summary

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510(k) Summary

Submitter's Name:	IGT, LLC dba Eigen
Submitter's Address:	13366 Grass Valley Avenue, Grass Valley, CA 95945
Submitter's Telephone:	530-274-1240
Contact Name:	William Mandel
Date Summary was Prepared:	21 Oct 2011
Trade or Proprietary Name:	Multi-Modality Image Fusion
Common or Usual Name:	Multi-Modality Image Fusion
Classification Name:	System, Image Processing, Radiological, LLZ Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
Syntegra	K041182
UniSyn	K081987
Aegis Navigation	K093672
Abaris	K053610

Intended Use

Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting.

Description of the Device and Summary of the Technological Characteristics:

Multi-Modality Image Fusion (MMIF) is software, which comprises of two software components, which is referred to as offline and online. The offline component pertains to the preparation of gland and suspected lesion boundaries on a DICOM image file days or hours prior to the biopsy procedure. The online component fuses the DICOM image files, which were, prepared on the offline component, with a snap shot incoming TRUS image. Each of the two software components can work together or independently.

Offline Software

The offline software can delineate suspected areas of interest using visualization and save this data in a standard format, e.g. as a surface mesh in VTK or STL format. Furthermore, the

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offline software can optionally delineate the gland boundary from a DICOM image, or other volumes where the boundary can be easily observed. This addition data is also saved in a standard format, e.g. surface mesh in VTK or STL or as a binary volume. This software would be typically executed by Radiologists.

Online Software

The online unit software is designed to fuse two images by entering a fusion mode and load the DICOM image and the boundary data provided by the offline unit. The online unit performs rigid alignment, either selecting globally align that orients the two DICOM volumes based on the known relative orientation difference between the two or specify landmarks to register images rigidly. The online unit then elastically warps the image to register on the incoming image from the offline unit.

The registered image volume is displayed on the incoming offline image frame of reference. Also overlaid on the incoming offline and registered image volumes annotating the suspected lesion boundaries. The two volumes are displayed side-by-side in a locked view. Rotation, slicing, panning, or zooming one of the volumes has the same effect on the other enabling visualization of similar features in both volumes simultaneously.

Plan targets on the volumes by selecting suitable locations within the suspected areas of interest boundary. When sufficient targets have been added, exiting fusion mode imports all targets planned in the offline frame of reference back to the original reconstructed ultrasound volume. This is done based on the deformation field that was estimated from registration (rigid followed by elastic registration).

Substantial Equivalence:

Manufacturer	**Eigen**	**ADAC Laboratories**	**Convergent Imaging Solutions**	**Sentinelle Medical Inc.**	**Traxtal Technologies lhc.**
Product Name	**Multi-Modality Image Fusion**	**Syntegra**	**UniSyn**	**Aegis Navigation**	**Abaris**
510(k) number	pending	K041182	K081987	K093672	K053610
Intended Use	Multi-Modality Image Fusion is a software application used by	Syntegra is a software application for multi-modality	UniSyn is a software application for image	This device provides two and three-dimensional image review,	ABARIS is a stereotaxic accessory for Computed

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	physicians in the clinic or hospital for 2-D and 3-D visualization, multi-modality image registration, and fusion of medical images. Additional software features include database management, communication, surface rendering, segmentation, ROI delineation, measurements, and reporting.	image registration and diagnostic fusion. Images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined functional and anatomical data providing different angular perspectives for interpretation by trained professionals	registration and fusion display of scanned image data from CT, PET, SPECT and MR scanners. UniSyn creates multi-planar reformat and maximum intensity projection displays of the data and provides measurements such as area, volume and Standard Uptake Values for user defined regions on the image	manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices. This device is intended to assist skilled medical professionals in clinical screening and	Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. it displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device. The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for

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				interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.	visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.
Where Used	Office settings in clinic or hospital	Office settings in clinic or hospital	Office settings in clinic or hospital	Not specified	clinical interventions
Software Device	Yes	Yes	Yes	Yes	Yes
Image Registration	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration	Multi-modality image registration	Yes
Image Fusion /Overlay Display	Fused overlay of images from multiple modalities	Fused overlay of images from multiple modalities	Fusion overlay of images from multiple modalities	overlay of images from multiple modalities	Yes
Opacity Control	Yes	Yes	Yes	Not Specified	Not Specified
3-D Rendering	Yes	Yes	Yes	Yes	Yes
Surface Rendering	Yes	Yes	Yes	Yes	Yes
Regions of interest	Yes	Yes	Yes	Yes	Yes
Configura	Yes	Yes	Yes	Yes	Yes

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ble image layouts					
3D Contouring	Yes	Not Specified	Yes	Yes	Yes
Export of 3D contours for planning	Yes	Not Specified	Yes	Not Specified	Yes
Image Storage and Communication	DICOM, JPEG	DICOM (check)	DICOM	DICOM	DICOM
Modalities	CT, MRI, Ultrasound	Positron Emission Tomography (PET) and X-ray Computed Tomography (CT).	CT, PET, SPECT and MR scanners	MRI, US, SPECT, CT, PET, Fluoroscopy, Endoscopy and others	Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems

The product's technical features are substantially equivalent to Syntegra (K041182), UniSyn (K081987), Aegis Navigation (K093672) and Abaris (K053610). The Multi-Modality Image Fusion is a software product that runs on PC-based workstations. Image data is input to the devices and used to generate 3-D views and perform image processing. Like the four predicate devices, the software has image measurement, multi-planar reformatting, segmentation and image registration abilities, fusion of images from different modalities, image storage and retrieval, as well as patient information management functions.

The Syntegra and UniSyn are software products that accept multiple image data types including magnetic resonance, and computed tomography. Aegis Navigation and Abaris are systems that accept multiple modalities that include magnetic resonance, computed tomography and ultrasound. The Multi-Modality Image Fusion has been designed for processing medical images in standard DICOM format. The system is composed of two modules: an offline and an online module for image fusion for planning a procedure.

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Testing and Performance Data:

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were developed and were used to verify system performance.

The device has been designed and manufactured to conform to the following standards:

ACRINEMA PS3.1-3.18 Digital Imaging and Communications in Medicine (DICOM)

ISO 14971 Application of Risk Management to Medical Devices

ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

The following tests were performed:

MMIF Hardware verification Test Procedure

MMIF Online Verification Test Procedure

MMIF Offline Software Application Verification Test Procedure

MMIF Risk Mitigation Verification Test Procedure

Registration Accuracy for Clinical Data (bench test)

Phantom Volume Measurements (bench test)

Phantom Registration Accuracy (bench test)

All the above mentioned tests passed. Theses testing activities were conducted to establish the performance, safety, effectiveness, functionality usability, and reliability characteristics of the new device.

The purpose of the performance testing (bench testing) was to ensure the performance of the new MMIF software by verifying the accuracy of the specifications and simulating real customer data collected from the hospital setting.

The conducted verification tests have confirmed static and dynamic performance of the complete system consisting of both the online and off line software installed on specified hardware. Furthermore these tests establish compliance to the specification under conditions simulation real environment of use.

Conclusion:

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of the Multi-Modality Image Fusion with those of the two predicate devices demonstrate that the Multi-Modality Image Fusion is substantially

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equivalent to existing products on the market today.

The verification and validation testing included bench performance tests, functionality tests, and system test. All tests were successfully completed.

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Section 2

User Manual

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Multi-Modality Image Fusion

innovation by eigen

User Manual
790-07000-10 Rev C

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790-07000-10 Rev D
U.S. and foreign patents pending
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Technical Writer–Chris Morton

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Case Manager

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Image Viewer

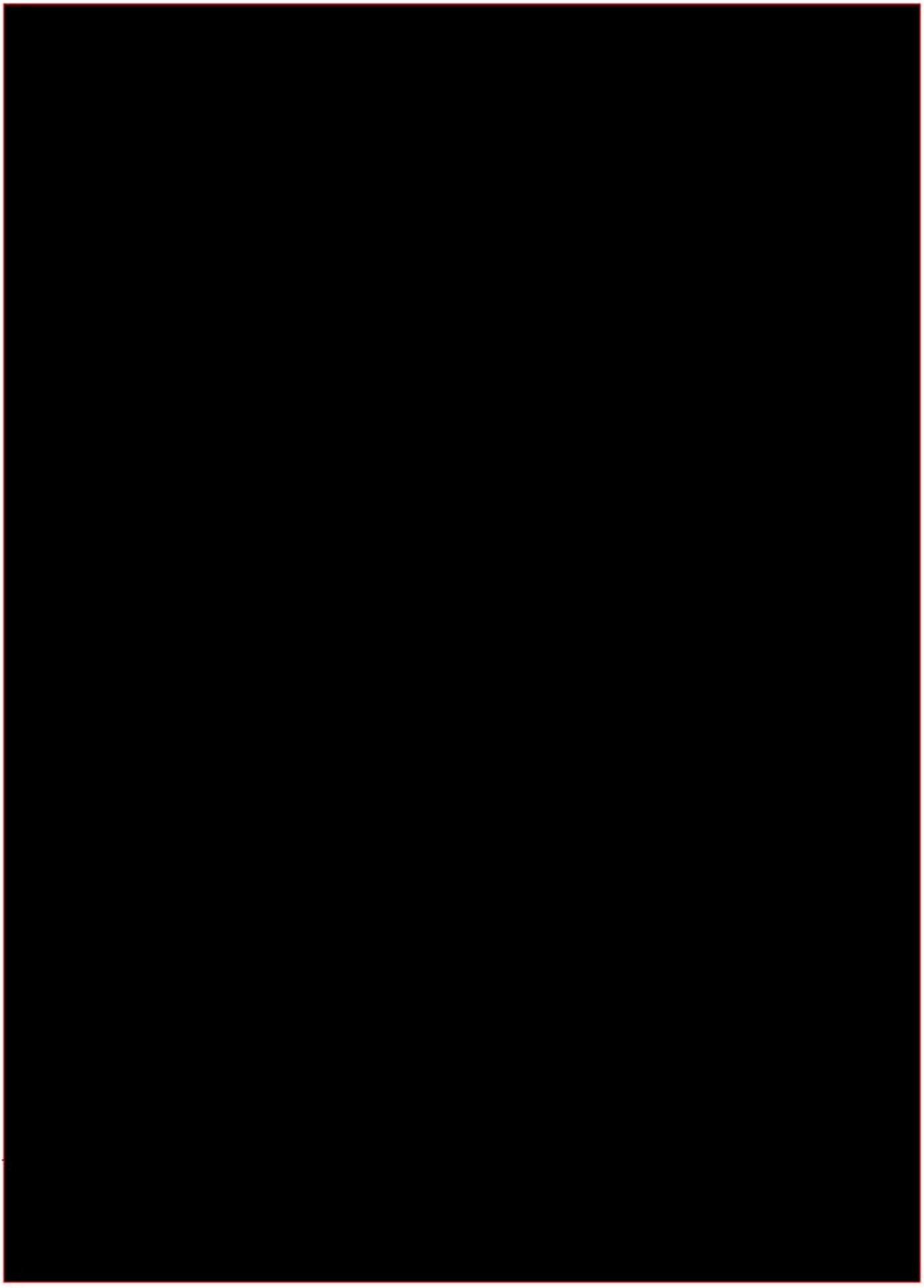

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Image Viewer

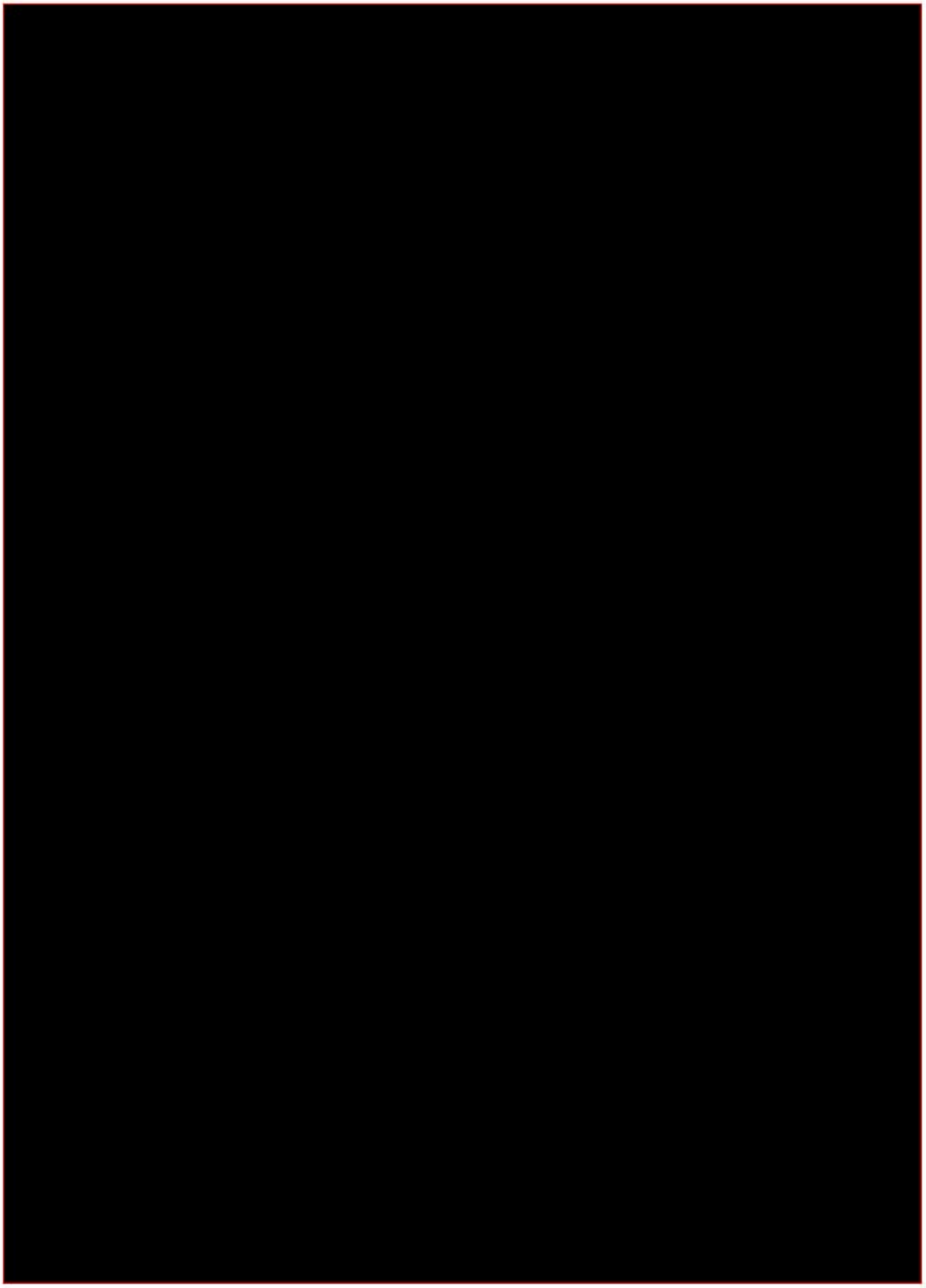

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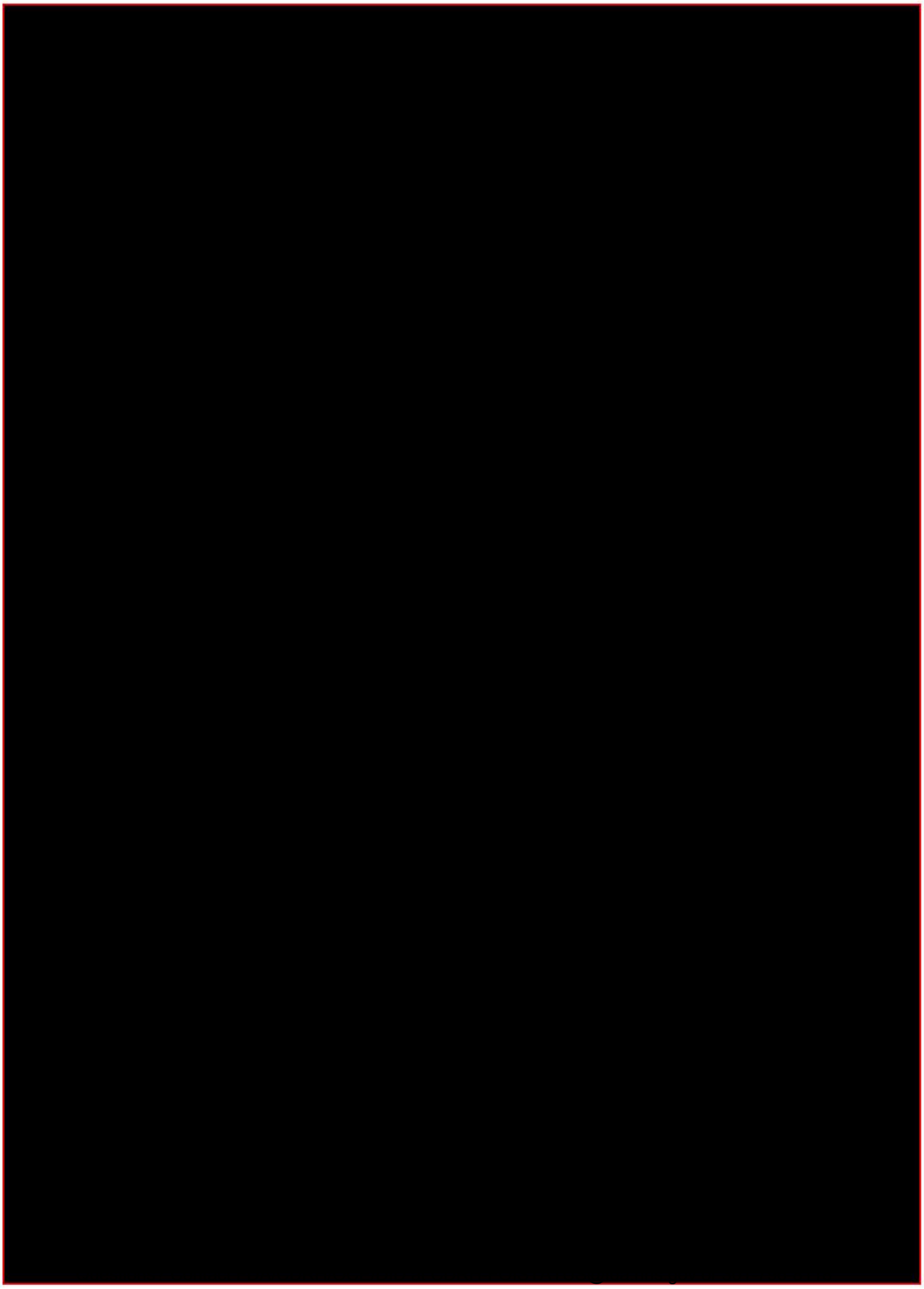
Image Viewer



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Appendix B

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Section 3

Additional Predicate Devices

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K093672

510(k) Summary of Safety and Effectiveness for: Aegis Navigation and Aegis Pelvic Application

DEC 11 2009

I. Manufacturer

Sentinelle Medical Inc.
555 Richmond Street West,
Suite 800, P.O. Box 301,
Toronto, ON
Canada M5V 3B1

II. Contact Person

Joan Medley
Director, Regulatory and Quality
Tel: (647)258-3606
Fax: (416) 594-9696

III. Product Name/Classification Name

Product Name:	Aegis Navigation Aegis Pelvic Application
Common Name:	Medical Image Processing Software System
Classification Name:	Image processing system, Class II as described in CFR 21 892.2050
Product Code:	LLZ

IV. Date Prepared

November 16, 2009

V. Device Description

Aegis Navigation and Aegis Pelvic Application products are line-extensions to Sentinelle's medical image software product Aegis. These are also referred to below as (Aegis) plug-ins.

The products are designed to assist with multi-modality (including MRI, US, SPECT, CT, PET, Fluoroscopy, Endoscopy and others) imaging and guidance of screening and interventional procedures for anatomical structures such as head and neck, thoracic, breast, abdominal and pelvis(including prostate).

Aegis Pelvic Application is a software tool intended for analyzing multi-modality images. This plug-in also identifies where and how deeply, a biopsy or localization needle should be inserted into a region of interest (including prostate and surrounding structures) to strike a target or region of interest. Registration of target anatomy with an interventional device can be performed manually or automatically based on fiducial markers. This in turn provides a calculation of the location and depth of the targeted region of interest.

Similarly, Aegis Navigation is a software tool intended for analyzing multi-modality images. This plug-in also identifies where an imaging device (e.g. an ultrasound transducer), interventional tool (e.g. a biopsy or localization needle) or other tracked instrument should be placed in order to visualize or strike a target or region of interest. In addition, Aegis Navigation provides the user with the option to view previously acquired DICOM data (e.g. MRI data) alongside of a separate imaging modality such as Ultrasound (US) or a fluoroscopic device. In the context of US, a 3-D

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K053610

510(k) Summary of Safety and Effectiveness for ABARIS

APR 19 2006

I. Manufacturer

Traxtal Technologies Inc.
49 Spadina Ave. Suite 402C
Toronto, Ontario
Canada M5V2J1

II. Contact Person

Dr. Neil Glossop, President
Traxtal Technologies Inc.
Tel: 416-603-8349
Fax: 416-603-8354

III. Product Name/Classification Name

Product Name:	**ABARIS**
Common Name:	**Computer assisted, image-guided surgery system**
Classification Name:	**Computed Tomography X-ray System** **Class II as described in 21 CFR 892.1750**
Product Code:	**JAK**

IV. Date Prepared

December 19, 2005.

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V. Device Description

The ABARIS is a computer assisted, image guided surgery system. It guides a surgical instrument to a target that has been defined by the physician. The target can be indicated either preoperatively or intraoperatively using images or relative to an indicated position on the patient.

The ABARIS provides real-time, three-dimensional visualization and navigation tools for all stages of surgery including preoperative planning and intra-operative navigation. ABARIS transforms two-dimensional patient images (scan sets), derived from Computed Tomography (CT), Magnetic Resonance Imaging (MR), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Ultrasound (US), Fluoroscopy etc. into dynamic representations on which a tool can be navigated. The system performs spatial mapping from one image space to another image space or from image space to physical space ("registration") allowing the physician to correlate scan sets with each other and to the patient. The system facilitates minimally invasive surgical procedures. Like other commercially available image guided surgery systems, the ABARIS also offers computer assisted image-free and registration free navigation using the same instrumentation.

Targeted use areas for ABARIS include hospital operating rooms, outpatient surgery centers and procedure rooms.

VI. Intended Use

ABARIS is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. It displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.

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VII. Substantial Equivalence

The technological characteristics of the ABARIS are the same or similar to those found in the predicate devices. The ABARIS is substantially equivalent to the following four FDA cleared frameless stereotaxic systems:

System Name	Manufacturer	510(k) approval number
Ultraguide	Ultraguide Ltd.	K023227, K022354, K013150, K011418, K002258, K974432
StealthStation System	Medtronic Navigation, Inc.	K050438, K043088, K030552, K030106, K022126, K021980, K022414, K020338, K012937, K003201, K001284, K992461, K992927, K990214, K983670, K983397, K981768, K981686, K981684, K974187, K974161, K972398, K963173, K954276
CBYON Surgical Operating System	Cbyon, Inc.	K000171, K012886
Instatrak	GE Medical Systems Navigation and Visualization	K960330, K981998, K982994, K983529, K994270,K003510, K040050

The device labeling contains instructions for use. It includes indications for use, cautions, contraindications, warnings, and planning guidance. This information assures safe and effective use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Neil Glossop, Ph.D.
President
Traxtal Technologies
49 Spadina Avenue, Suite 402C
Toronto, Ontario, M5V 2J1
CANADA

Re: K053610
Trade/Device Name: ABARIS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 24, 2006
Received: March 27, 2006

Dear Dr. Glossop:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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/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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Applicant: Traxtal Technologies Inc.

510(k) Number (if known): Not yet assigned K053610

Device Name: ABARIS

Indications for Use:

ABARIS is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. It displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use ___ (Per 21 CFR 807 Subpart D)

David A. Lagerman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053610

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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tracking system provides positional data regarding the transducer, which is used to guide the real-time reformatting of DICOM data to match the current US image. Interventional and imaging device operation and manipulation remains under the manual control of the trained medical professional at all times.

Additional applications of Aegis Navigation include:

- The ability to display the position of a tracked probe or instrument, overlaid on DICOM (e.g.MR or CT) data
- The ability to track the position of an US transducer as it collects data, then retrospectively display reformatted DICOM (e.g. MR/CT) data slices oriented to match the previously acquired ultrasound images.

VI. Intended Use

This device provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices.

This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices.

This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.

VII. Substantial Equivalence

Sentinelle's Aegis Navigation and Aegis Pelvic Application are substantially equivalent to:

Device Name:	**Eigen 3D-Imaging Workstation**
Manufacturer:	Eigen LLC
510(k) Number:	K081093
Decision Date:	May 1, 2008
Decision:	Substantially Equivalent

Device Name:	**Aegis**
Manufacturer:	Sentinelle Medical Inc.
510(k) Number:	K070244
Decision Date:	February 9, 2007
Decision:	Substantially Equivalent

Device Name:	**Abaris**
Manufacturer:	Traxtal Inc.
510(k) Number:	K053610

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Decision Date:	April 19, 2006
Decision:	Substantially Equivalent

Sentinelle's Aegis Navigation and Aegis Pelvic Application are software plug-ins for use in conjunction with our legally marketed device, Sentinelle Aegis [K070244]. As such, Aegis Navigation and Aegis Pelvic Application inherit much of their functionality from the approved device.

Table 2 lists the technological characteristics, as derived from the Indications for Use and the Device Description of Aegis Navigation and Aegis Pelvic relative to the Sentinelle Aegis, Eigen 3D-Imaging Workstation and Traxtal Abaris predicate devices. The technological characteristics of Aegis Navigation and Aegis Pelvic Applications are the same or equivalent to those found in the predicate devices, as demonstrated in Table 2 below.

A high level summary of the comparison is as follows:

1) From the Aegis predicate to the current submission, clinical screening and interventional capabilities are extended to include any anatomical structures where imaging is currently used for visualizing such structures. All of the visualization, analysis, measurement and display functionality employed are equivalent to the Aegis predicate device so no new issues of safety and effectiveness arise for screening. For interventional guidance, registration of MR image DICOM coordinates to physical patient coordinates is done using the same functionality as the Aegis predicate. This, combined with the conducted test results show that the software is accurate and functions as specified, and no new issues of safety and effectiveness arise.
2) From the Aegis predicate to the current submission, Aegis Navigation adds the ability to manipulate image display based on tracked data acquired from 3D positioning devices. The interface to the positional tracking device is accomplished in the same manner as the Abaris predicate, and the registration of spatially tracked instruments to coordinates in the image space is accomplished in the same manner as the Abaris and Eigen predicates. This, combined with the conducted registration and targeting tests of Aegis Navigation show that spatial tracking functionality is accurate, functions as specified, and no new issues of safety and effectiveness arise.

The device labeling includes the Operator's Guide (User Manual) which includes indications for use, cautions, warnings, contraindications and instructions. This information assures safe and effective use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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VIII. Testing and Performance Data

Testing for Aegis Navigation and Aegis Pelvic Application was performed to ensure that all functional requirements have been met, and that core functions execute as expected. Testing was conducted in-house by trained personnel in a simulated work-environment using phantoms or volunteers to obtain the functional and accuracy test results.

Registration accuracy tests were performed to ensure that the registration and correspondence between MR and ultrasound meets or exceeds specified criteria. Needle verification tests were also performed to ensure that needle registration and targeting results met or exceeded specified criteria. The test methodology employed was identical to that of the Aegis predicate device, conducted by targeting locations within a phantom and confirming that the selected target location/needle location based on the registration calculation is within the same tolerance range or better than the Aegis predicate device. The completed test procedures and results are presented in the following appendices:

Appendix Z1a – Navigation Software Verification Specifications [SMI-0997]
Appendix Z1b- Navigation Software Verification Results [SMI-0337]
Appendix Z1c – Navigation System Accuracy Specifications [SMI-0258]
Appendix Z1d – Navigation System Accuracy Test Results [TR-0326]
Appendix Z2a & Z2b – Pelvic Software Verification Specifications including Accuracy [SMI-917]
Appendix Z2c - Pelvic Software Verification Results including Accuracy [SMI-1059]

Aegis Navigation and Aegis Pelvic Application's indications for use are a combination of the indications for use of three legally marketed predicate devices: Sentinelle's Aegis, Traxtal's Abaris and Eigen's 3D-Imaging Workstation. Aegis Navigation and Aegis Pelvic Application combine the features of these predicate devices and do not provide novel functionality.

As such, the features provided by Aegis Navigation and Aegis Pelvic Application do not in themselves raise new concerns of safety or effectiveness.

Test Conclusion

The results of these tests demonstrate that the system accuracy is within specification and performs as well as, or better than Aegis, the legally marketed predicate device. Comparison to the other predicate devices is not directly possible since the testing methodology and accuracy specifications are not publicly available. Over two years of extensive clinical use of the Aegis predicate device shows that the specified accuracy and the accuracy testing methodology of the Aegis predicate provide safe and effective targeting of instruments to image-identified target locations.

As such, Aegis Navigation and Pelvic Application software plug-ins are as safe and effective as the predicate devices and are substantially equivalent to existing products on the market today. The software performs as well as, or better than legally marketed predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

Sentinelle Medical, Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

DEC 11 2009

Re: K093672
Trade/Device Name: Sentinelle Aegis Navigation & Sentinelle Aegis Pelvic Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 25, 2009
Received: November 27, 2009

Dear Mr. Rongero:

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); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indication(s) For Use

510(k) Number: K093672

Device Name: Sentinelle Aegis Navigation & Sentinelle Aegis Pelvic Application

Indications for Use:

This device provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices.

This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices.

This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.

Prescription Use (Part 21 CFR 801 Subpart D): ___√___ **AND/OR** Over-The-Counter Use (Part 21 CFR 801 Subpart C) _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093672

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 4

Addition Predicate Device Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Addition Predicate Device Marketing Material

Please note that Traxtal Technologies is associated with Philips and is the PercuNav system. Below are the marketing materials for the two systems Abaris K053610, now call PercuNav by Philips and Aegis Navigation K093672. Sentinelle Medical Inc.was purchased by Hologic.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PHILIPS
sense and simplicity

PercuNav

Image fusion and navigation

The Philips PercuNav system enables interventional radiologists to navigate tracked instruments to a region of interest when performing needle-based procedures using real-time ultrasound, previously acquired images, or a combination of these. PercuNav has been used clinically in biopsies, ablations and drainages.

Diagnostic radiologists using PercuNav benefit from fused images to help clarify diagnosis. The system may also be paired with Philips iU22 xMATRIX ultrasound system for state-of-the-art ultrasound navigation. PercuNav is the only computer-assisted, image-guided diagnostic and interventional system for soft tissue cleared by the U.S. FDA for all imaging modalities: ultrasound, CT, MR, rotational fluoroscopy (cone beam), and PET/CT.

+ Watch a video about PercuNav Image Fusion and the iU22 xMATRIX system

360° view of standalone PercuNav system

Key advantages

Enables matching of the region of interest on both live and pre-procedure images from multiple modalities
Guides interventional procedures by creating a single display of patient anatomy overlaid with instrument tip location
Enables image transfer from the iU22 xMATRIX ultrasound system to PercuNav via a digital navigation link for streamlining workflow

Create real-time, 3D maps for interventions

Like a GPS for medical instruments, the PercuNav system provides imaging tools to assist clinicians in ablation and biopsy procedures. It combines electromagnetic tracking of flexible or rigid instruments with patient images from multiple modalities to create a real-time 3D map of the patient space that displays the instrument position, orientation, and trajectory, as well as anatomical landmarks. This map helps guide physicians to areas of interest, even when they are small, hard to visualize, difficult to access, or close to sensitive organs, vessels, or tissue.

Capabilities

Tracking and displaying the tip position of needles and other instruments in real time on both live and pre-acquired images
Tracking a wide range of both flexible and rigid instruments, such as biopsy and ablation introducers, ultrasound trackers, probes, registration patches, and patient tracking devices for motion compensation
Providing out-of-plane approaches for targets that are difficult to image and access in the same plane
Assisting with subsequent needle placements during ablation procedures when there is "gas out" by using a fused ultrasound/CT image, rather than ultrasound alone
Planning of virtual procedures to enable clinicians to select targets and entry points, then virtually travel the selected path to check for obstacles
Potentially reducing the need to perform additional CT or fluoroscopy scans during interventions

Leverage the strength of your images

PercuNav image fusion enables users to leverage the strength of each modality to create an information-rich, fused image.

Capabilities

Display of corresponding data from multiple imaging modalities as overlaid and side-by-side images with areas of interest automatically marked on images
Easy localization and comparison of hard-to-find or ambiguous ultrasound targets by referring to related CT or MR images with corresponding areas of interest marked on the different modality images

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Aid in lesion documentation for oncology and therapy monitoring
Possible reduction of repeat ultrasound exams for interventional planning or device guidance
Possible reduction of the number of CT scans
Import segmented data sets from Philips Extended Brilliance Workspace (EBW) workstation

Product features include:

Ultrasound navigation
CT and MR navigation
Diagnostic workflow
PET/CT input
Fusion of ultrasound with other modalities
Trajectory and target planning
Respiratory gating and motion compensation
Automatic tool identification
Automatic registration
Network DICOM transfer
EBW segmented volume input
Import from rotational fluoroscopy (cone beam)
Instruments*

*A wide range of tracked instrumentation is available including biopsy devices, ablation introducers, ultrasound trackers, registration patches, and needles as small as 0.75 mm (22G). Please consult your Philips representative for details.

* Note: These products are available only in the U.S.A. Philips Tx2 mobile cart, PercuNav software, and associated tools are all components of Philips PercuNav system and are not sold separately. Please contact your Philips representative for further information on components and equipment compatibility and to place an order.

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http://www.healthcare.philips.com/us_en/products/ultrasound/systems/percunav/percunav.wpd
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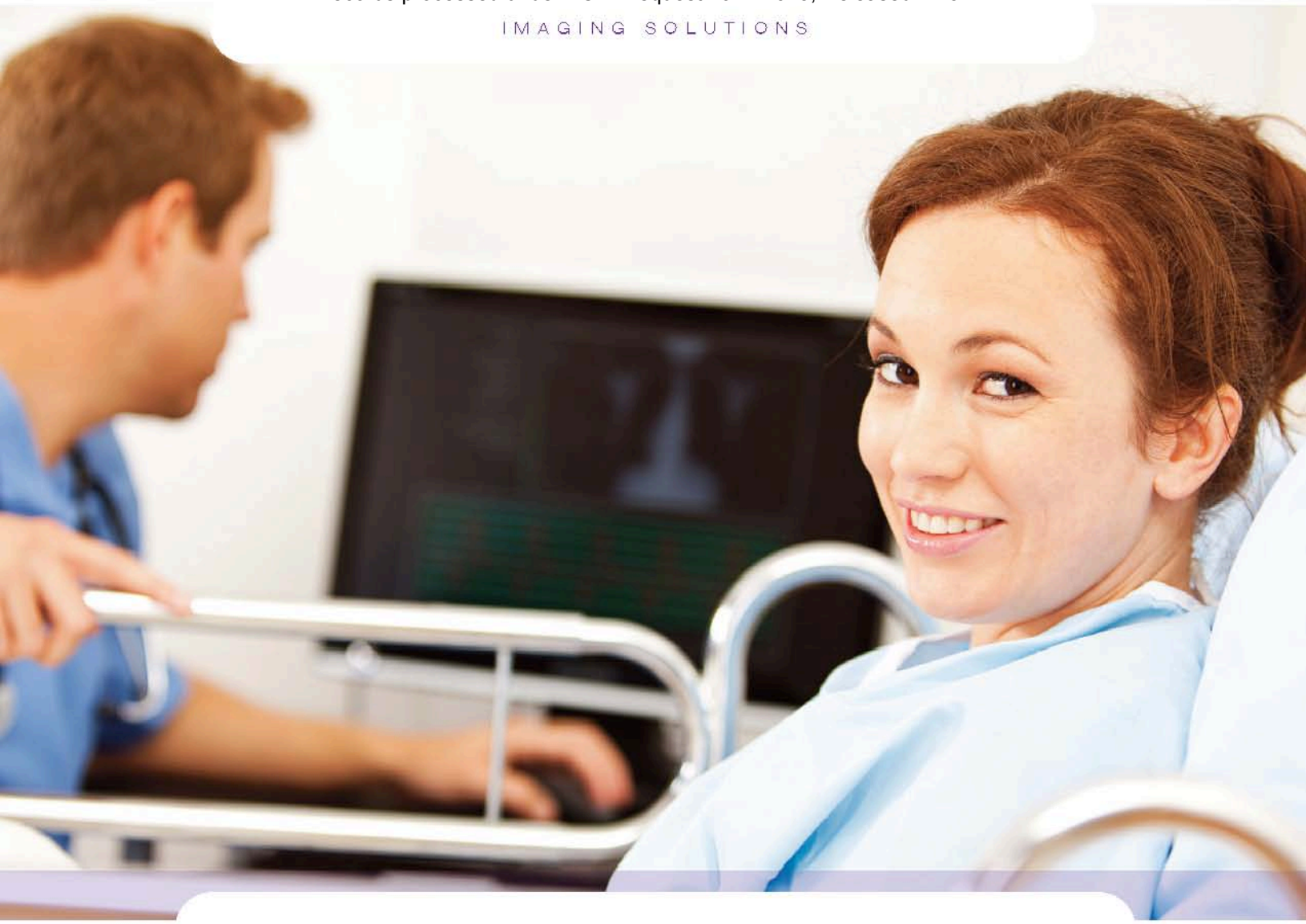
IMAGING SOLUTIONS



Aegis™ Navigation

Multi-Modality Solution

HOLOGIC®

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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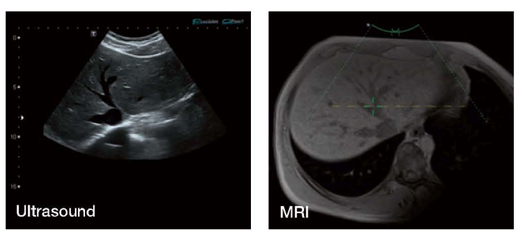
Improve visualization and increase diagnostic options by combining your ultrasound imaging with **3D MRI or CT images**

Aegis™ Navigation acts as a real-time GPS of previously acquired MR/CT images to guide your ultrasound procedure. Leverage the strengths of multi-modality imaging to locate difficult lesions and navigate complex anatomy.

Aegis Navigation Workstation with Ultrasound Unit



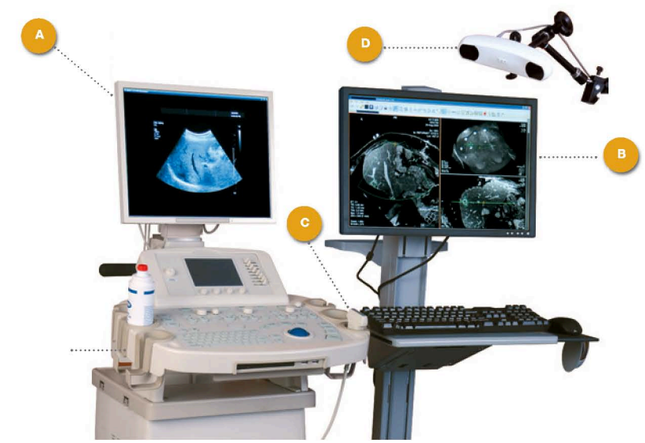
Co-registered US and MR images of the liver, enlarged

Optimizing image quality and workflow

- Increase diagnostic confidence with precise spatial correlation of MR/CT and ultrasound images in real-time.
- Improve your ability to locate small and poorly visualized regions using ultrasound, and increase throughput on imaging resources.[1]
- Real-time 3D rendering of the tissue helps to orient the user relative to the patient's anatomy.
- Aegis Navigation software built on the Aegis 3D advanced imaging platform leverages powerful image processing functionality.
- Compatible with all other Aegis plug-ins, enabling features such as registration of reconstructions (e.g. DCE colour maps) to real-time ultrasound images.

Platform independent navigation

- Combine the Aegis Navigation solution with your existing ultrasound machine. Our technology is compatible with most commercially available ultrasound systems.



Platform Independent Navigation Solution

A. Ultrasound system display
B. Aegis Navigation software showing matched MR image
C. Tracked ultrasound transducer
D. Optical camera

COMBINING MODALITIES YIELDS MORE DEPENDABLE RESULTS.

[1] Evaluation of a new multi-modality visualization tool for investigation of hepatic metastases from colorectal cancer.
L. Milot[1], K. Ma[2], E. Efford[1], G. Sela[2], C. Maloney[1], S. Crisp[1], N. Coburn3, M. Haider[1], C. Piron[2], C. Law[3], and D. Plewes[4].

[1] Department of Medical Imaging, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada,
[2] Sentinelle Medical Inc, Toronto, Ontario, Canada,
[3] Department of Surgical Oncology, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada,
[4] Department of Imaging Research, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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At Hologic, we are dedicated to solving the real problems that radiologists, technologists, and surgeons encounter in the detection and treatment of cancer. Our suite of advanced technologies for Magnetic Resonance Imaging and intervention creates integrated, flexible, and dedicated systems committed to addressing the continuum of care.

BREAST IMAGING SOLUTIONS | INTERVENTIONAL BREAST SOLUTIONS | BONE HEALTH
PRENATAL HEALTH | GYNECOLOGIC HEALTH | MOLECULAR DIAGNOSTICS

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Fax: +1.781.280.0668

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118