



Food and Drug Administration
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Silver Spring, MD 20993-0002

EDDA Technology
% Daniel Kamm
Submission Correspondent
5 Independence Way
PRINCETON NJ 08540

November 20, 2015

Re: K151414
Trade/Device Name: IQQA-Guide
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 22, 2015
Received: October 27, 2015

Dear Mr. Kamm:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151414

Device Name
IQQA-Guide

Indications for Use (Describe)

The IQQA-Guide System is a stereotactic accessory for Computed Tomography (CT). It displays simulated image of interventional instruments (such as biopsy needle, ablation needle, probe) on a computer monitor that also shows an imaging-based 3D model of the patient anatomy, and the current and the projected future path of the interventional instruments.

The system supports the imaging-based model derived from physician's confirmed segmentation results of patient's image scans, including intra-operative CT, pre-procedural CT, and CT or MR previously acquired before surgical procedures. Additionally, overlaying ultrasound images (when available) may be displayed with the model of patient anatomy.

The system supports a workflow based on automated image registrations of spatial mapping from one image space to another image space, or from image space to physical space. Physician may interactively adjust and confirm registration results, and evaluate 3D visualization and quantitative information in terms of distance, size, and spatial location associated with patient anatomy and instruments.

The system is intended for intra-operative guidance for surgical procedures. It is intended for use by trained physicians in clinical intervention and for structures where imaging is currently used for visualizing such procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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EDDA Technology 510(k) Summary K151414

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Contact: Xiaolan Zeng, Executive Vice President

Date prepared: November 14, 2015

1. Identification of the Device:

Proprietary – Trade Name: IQQA-Guide

Common Name: Computer assisted image-guided system

Classification Name: Computed Tomography X-ray System

Regulation Number: 21 CFR 892.1750

Regulatory Class: Class II

Product Code: JAK

2. Substantially equivalent legally marketed devices:

Manufacturer	Name of the Predicate Device	FDA 510(k) Number	FDA Clearance Date	CFR/Product Code
Veran Medical Technologies	ig4 Image Guided System	K093995	01/27/2010	21 CFR892.1750 JAK
Traxtal Technologies	ABARIS, Computer assisted, image-guided system	K053610	04/19/2006	21 CFR892.1750 JAK

3. Indications for Use (intended use):

The IQQA-Guide System is a stereotactic accessory for Computed Tomography (CT). It displays simulated image of interventional instruments (such as biopsy needle, ablation needle, probe) on a computer monitor that also shows an imaging-based 3D model of the patient anatomy, and the current and the projected future path of the interventional instruments.

The system supports the imaging-based model derived from physician's confirmed segmentation results of patient's image scans, including intra-operative CT, pre-procedural CT, and CT or MR previously acquired before surgical procedures. Additionally, overlaying ultrasound images (when available) may be displayed with the model of patient anatomy.

The system supports a workflow based on automated image registrations of spatial mapping from one image space to another image space, or from image space to physical space. Physician may interactively adjust and confirm registration results, and evaluate 3D visualization and quantitative information in terms of distance, size, and spatial location associated with patient anatomy and instruments.

The system is intended for intra-operative guidance for surgical procedures. It is intended for use by trained physicians in clinical intervention and for structures where imaging is currently used for visualizing such procedures.

4. Description of the device:

The IQQA-Guide System is a stereotactic accessory for Computed Tomography (CT). It utilizes electromagnetic tracking technology to locate and navigate instruments relative to an imaging-based model of the patient anatomy. IQQA-Guide displays the simulated image of interventional instruments (such as biopsy needle, ablation needle, probe) on a computer monitor that also shows

the imaging-based 3D model of the patient anatomy, and the current and the projected future path of the interventional instruments.

IQQA-Guide supports the imaging-based 3D model derived from physician’s confirmed segmentation results of patient’s image scans, including intra-operative CT, pre-procedural CT, and CT or MR previously acquired before surgical procedures. The model of segmentation results may also be loaded from saved reports of the IQQA-BodyImaging software (K141745). Additionally, overlaying ultrasound images (when available) may be displayed with the model of patient anatomy. The system supports a workflow based on automated image registrations of spatial mapping from one image space to another image space, or from image space to physical space. Physician may interactively adjust and confirm registration results, and evaluate 3D visualization and quantitative information in terms of distance, size, and spatial location associated with patient anatomy and instruments.

The IQQA-Guide system consists of an EM tracking system, software, and a computer system. The system is intended for intra-operative guidance for surgical procedures. It is intended for use by trained physicians in clinical intervention and for structures where imaging is currently used for visualizing such procedures.

The EM sensor and accessories that are compatible with the IQQA-Guide are cleared by the FDA in K092619, including eTRAX™ Needle System, General Purpose Sensor, and VirtuTRAX Instrument Navigator. They are not part of the IQQA-Guide system and are sourced separately.

The compatible EM sensor and accessories are connected to the submitted device IQQA-Guide by plugging the connector part of the K092619 sensor into the receptacles on the front panel of the EM tracking system contained in the IQQA-Guide.

The software contained in the submitted device IQQA-Guide (v1.0), is an upgrade from the already cleared IQQA-BodyImaging (K141745).

5. Comparison with predicate devices – IFU and Technological characteristics

	<i>Device of 510(k) submission:</i> IQQA-Guide (version 1.0)	<i>Predicate Device:</i> ig4 Image Guided System K093995	<i>Predicate Device:</i> ABARIS, Computer assisted, image-guided system K053610
Manufacturer	EDDA Technology	Veran Medical Technologies	Traxtal Technologies
Indications for Use	The IQQA-Guide System is a stereotactic accessory for Computed Tomography (CT). It displays simulated image of interventional instruments (such as biopsy needle, ablation needle, probe) on a computer monitor that also shows an imaging-based 3D model of the patient anatomy, and the current and the projected future path of the interventional instruments. The system supports the imaging-based model derived from physician’s confirmed segmentation results of patient’s image scans, including intra-operative CT, pre-procedural CT, and CT or MR previously acquired before surgical procedures. Additionally, overlaying ultrasound images (when available) may be displayed with the model of patient anatomy. The system supports a workflow based on automated image registrations of spatial mapping from one image space to another image	The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) or 3D fluoroscopic x-ray systems. The ig4 System is indicated for interventional displaying an instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays a CT-based or 3D fluoroscopic X-ray-based model of the target organ(s). The ig4™ System is additionally indicated for overlaying Ultrasound images onto the model of the target organ(s). The ig4™ System compensates for the patient’s respiratory phases. The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography, 3D fluoroscopic x-ray, or ultrasound are currently used for visualizing such procedures.	ABARIS is a stereotaxic accessory for Computed Tomography (CT), Magnetic (MR), Resonance, 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

	<i>Device of 510(k) submission:</i> IQQA-Guide (version 1.0)	<i>Predicate Device:</i> ig4 Image Guided System K093995	<i>Predicate Device:</i> ABARIS, Computer assisted, image-guided system K053610
	space, or from image space to physical space. Physician may interactively adjust and confirm registration results, and evaluate 3D visualization and quantitative information in terms of distance, size, and spatial location associated with patient anatomy and instruments. The system is intended for intra-operative guidance for surgical procedures. It is intended for use by trained physicians in clinical intervention and for structures where imaging is currently used for visualizing such procedures.		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.
Tracking technology	Electromagnetic tracking technology	same	same
Computer Hardware Configuration	standard PC hardware	standard PC hardware	standard PC hardware
User Interface	A graphical user interface for users to interact with the software, select tools and drive workflow	A graphical user interface for users to interact with the software, select tools and drive workflow	A graphical user interface for users to interact with the software, select tools and drive workflow
Instrument display	Displaying dynamically the simulated image of tracked instrument	same	same
Patient imaging display	Use of acquired patient imaging for anatomy structure: -CT during intervention -CT pre-procedural - Previously acquired CT, MR -Ultrasound during intervention when available	Use of acquired patient imaging for anatomy structure: CT, 3D fluoroscopic X-ray, ultrasound	Use of acquired patient imaging for anatomy structure: CT, MR, PET, SPECT, Ultrasound, Fluoroscopy etc
Combined display	Combine the display of simulated instrument and display of patient imaging/anatomy model	same	Same
clinical environment to be used in	Used in clinical interventions and for anatomical structure where imaging is currently used for visualizing such procedures	Used in clinical interventions and for anatomical structure where imaging is currently used for visualizing such procedures	For all stages of surgery. Including hospital operating rooms, outpatient surgery centers and procedure rooms
Used by	For use by trained physicians	same	same

IQQA-Guide has the same intended use and similar technological/functional features as the predicate devices in providing tools and workflow designs to support physician users to visualize and evaluate tracked interventional instrument with respect to patient imaging data.

The IQQA-Guide device is utilized only by trained professionals. The trained professionals, providing ample opportunity for competent human intervention interpret images and information being displayed. They are competent to determine whether the images and information being displayed can be useful in the decision of patient management. Physicians make all final patient management decision.

IQQA-Guide and predicate devices are substantially equivalent in the areas of technical characteristics, principles of operation, and functional features. IQQA-Guide does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

6. Safety and Effectiveness:

The IQQA-Guide labeling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via the company’s design control and risk management procedures. Potential hazards are controlled via development and verification and validation testing. The device complies with the following standards:

1	Standards No.	Standards Organization	Standards Title	Version	Date
	PS 3.1 - 3.18 (2009)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set	3	2009
2	Standards No.	Standards Organization	Standards Title	Version	Date
	ANSI/AAMI/IEC 60601-1	ANSI/AAMI/IEC	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Third Edition, Amendment 1 2012).	3Ed	2012
3	Standards No.	Standards Organization	Standards Title	Version	Date
	ANSI/AAMI/IEC 60601-1-2	ANSI/AAMI/IEC	Medical Electrical Equipment, Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests, 4th Ed. (2014).	4 th Ed	2014

7. Testing Information and Performance:

All product specifications were verified and validated. Testing was performed according to internal company procedures and applicable standards.

The system was tested for electromagnetic compatibility and electrical safety according to the IEC60601-1 and IEC 60601-1-2 standards.

Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals.

Additionally, to supplement system and software validation for IQQA-Guide, the company has conducted testing at clinical site. The purpose of the testing is to have physicians use the IQQA-

Guide during clinical interventional procedures, validate major functionalities provided by the system, and provide feedback along the line of the intended use of the system.

Regarding system registration performance, experiments involving intervention on phantoms showed accuracy of $2.35 \pm 1.23\text{mm}$ and $2.23 \pm 0.82\text{mm}$ at two hospital sites respectively, and experiments involving patient studies showed accuracy of $4.62 \pm 3.07\text{mm}$ and $4.9 \pm 1.9\text{mm}$ at two hospital sites respectively.

In all instances, test results support the conclusion that actual device performance satisfies the design intent.

8. Conclusion

The IQQA-Guide has the same intended use as the predicate devices. Test results demonstrate that the device is safe, effective, and does not raise any new potential safety risks. In all material respects, the IQQA-Guide is substantially equivalent to the predicate devices.