IGI Technologies
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

August 16, 2018

Re: K180522
Trade/Device Name: IGTFusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 16, 2018
Received: July 16, 2018

Dear E.J. Smith:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

Section 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K180522

Device Name
IGTFusion

Indications for Use *(Describe)*

IGTFusion is a stand-alone software product that provides the physician 3 means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning, interventional radiology and other medical Specialties. IGTFusion is not intended for mammography diagnosis.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 5

510(k) Summary

Submitter: IGI Technologies
387 Technology Drive
College Park, MD 20742

Contact Person: Will Plishker, PhD
CEO
Telephone Number: 202-713-9571
Email: will@igitechnologies.com

Summary Preparation Date: February 22, 2018

Device Description:

Trade Name: IGTFusion

Common Name: Picture Archive and Communication Systems

Classification Name: Picture Archive and Communication Systems

Regulatory Class: Class II

Product Code: LLZ

C.R.F. Section: 21 CFR 892.2050

Predicate Devices:

	Manufacturer	Brand Name	510(k) Number
Primary	Velocity Medical Solutions, LLC	VelocityAIS	K081076
Reference	Mirada Medical Ltd LLC	RTx	K130393

Device Description:

The purpose of IGTFusion is to assist the user with the visual evaluation, comparison, and merging of information between anatomical and functional images from a single patient. The user needs to take into consideration the product's limitations and accuracy when integrating the information from the registration results for final interpretation. IGTFusion does not replace the usual procedures for visual comparison of datasets by a user. Fusion images are intended to provide additional information to a user's existing workflow for patient evaluation.

The potential hazards associated with this software product are no different from those of other PACS components and may be variously obviated by decisions made by the user of the product. None of these failures are expected to contribute to patient death or injury. In consequence, IGTFusion is considered to have no adverse effect on health since the results represent only a part of the information that a user will utilize for final interpretation. In this regard, IGT Fusion represents a moderate level of concern with respect to patient safety.

Indications for Use:

IGTFusion is a stand-alone software product that provides the physician 3 means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning, interventional radiology and other medical Specialties. IGTFusion is not intended for mammography diagnosis.

Intended Use:

The purpose of IGTFusion is to assist the user with the visual evaluation and comparison of information between anatomical and functional images from a single patient. The supported modalities are CT, PET, and MR.

Substantial Equivalence Discussion:

Discussion of Technological Similarities:

IGTFusion, Mirada RTx and VelocityAIS have the same visualization capabilities, registration, DICOM Compliance and each has a Graphical User Interface.

IGTFusion and VelocityAIS both have same reporting capabilities.

Discussion of Technological Differences:

While the core features of IGTFusion match with existing predicate devices, the packaging of how those features are delivered are different. Instead of providing a complex workstation with many extra features for interaction and visualization, IGTFusion provides only the essential representations to streamline the process of utilizing fusion visualization. Instead of requiring a clinician to sit at a workstation or log on remotely to a software GUI, IGTFusion is more like a fusion appliance, providing quick fusion visualization with a minimum of interaction required. After a floating image is selected, clinicians may push a series of interest from PACS or even directly from imaging equipment for quick visualization. Such minimal activity also lends itself more easily into larger workflow processing pipelines which are generating and consuming images for more complex applications. This approach is founded on our image registration engine which has been extensively tested to show that is as accurate existing solutions without the need of extra tools. This general approach also lends itself to avoiding advanced visualization features such volume rendering and annotations, which strictly enhance (i.e. are not required for) image fusion. These differences raise no new issues of safety and effectiveness.

Non-Clinical Performance Standards:

- AAMI / ANSI / ISO 14971:2007/(R)2010 (Corrected 4 October 2007), Medical devices - Applications of risk management to medical devices
- AAMI / ANSI / IEC 62304:2006, Medical device software - Software life cycle processes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005

Clinical Studies:

No clinical studies were conducted.

Conclusion:

The proposed device (IGTFusion) does not result in any new potential safety risk and performs in accordance with its intended use as well as comparatively with the intended use of the chosen predicates. We conclude that IGTFusion is as safe and effective as the predicate device and poses no unanswered questions regarding safety and efficacy.