IGROK™
Image Understanding Solutions

K080325

APR - 8 2008

510(k) Summary

Sponsor Information

Company Name & Address:	iGrok, LLC 234 Graham St, Ste 200, Sewickley, PA 15143
Contact:	Robert Riker, President 412-398-5841 412-741-3238 (shared fax, set up w/ voice call)
Summary Date:	February 1, 2008

Device Information

Common or Usual Name:	Image Processing System, Radiology
Proprietary Name:	IGROK
Classification Name:	PACS, 21 CFR 892.2050

Predicate Device(s)

VelocityAIS (K070248)

Description of Device

IGROK is a computer hardware and software system which is intended to facilitate Image-Guided Radiation Therapy (IGRT) by consolidating and organizing a wide array of data pertaining to a patient's course of external beam radiation therapy, and presenting this data, along with relevant analyses, so as to efficiently support typical IGRT review and decision-making tasks. The system functions as a radiation therapy-specific PACS, providing storage and visualization for DICOM diagnostic imaging, treatment plans, dose volumes, RT images, and structure set data. In addition, registration is provided between image volumes using both linear and non-linear techniques.

Indications for Use

IGROK is a hardware/software system that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Certain registration functions and analyses are only applicable in pelvic, head and neck areas. IGROK is not intended for mammography diagnosis.

Comparison with Predicate Device(s)

IGROK is substantially equivalent to the predicate device VelocityAIS. IGROK is similar in characteristics, materials, features, has similar technological features, intended use and indications for use as the predicates, and does not pose any new issues of safety and effectiveness.

Non-Clinical Performance Summary

The IGROK software was designed, developed, verified, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validation, and maintenance.

The IGROK system will successfully complete verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been studied and controlled.

Conclusions

In summary, iGrok, LLC, is of the opinion that the IGROK system does not introduce any new potential safety risks, is as effective, and performs as well as devices currently on the market, and concludes that the IGROK system is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR - 8 2008

Mr. Robert J. Riker
President
iGrok, LLC
234 Graham Street, Suite 200
SEWICKLEY PA 15143

Re: K080325
Trade/Device Name: IGROK
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 1, 2008
Received: February 6, 2008

Dear Mr. Riker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. Indications for Use

510(k) Number: K080325

Device Name: IGROK

Indications For Use:

IGROK is a hardware/software system that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Certain registration functions and analyses are only applicable in pelvic, head and neck areas. IGROK is not intended for mammography diagnosis.

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080325