IKOEtech

EXPERTS AT YOUR FINGERTIPS

6223 RICHMOND AVENUE, SUITE 303
HOUSTON, TX 77057

TEL: (713) 600-2410
FAX: (713) 600-2411

E-MAIL: HCHAO@IKOEMED.COM
WEB SITE: HTTP://WWW.IKOETECH.COM

K083591

DEC 29 2008

Premarket Notification [510(k)] Summary

November 5, 2008

Trade Name:	*IKOEngelo*™ Software Version 2.0
Common Name:	Radiation Therapy Simulation accessory
Classification Name:	Radiation Therapy Simulation System,
	Product Code: KPQ (per 21 CFR 892.5840)
Manufacturer's Name:	IKOEtech, LLC.
Address:	6223 Richmond Avenue, Suite 303
	Houston, TX 77057
Corresponding Official:	Ms. Huimin Chao, LLM
Title:	President
Telephone:	(713) 600-2410
Fax:	(713) 600-2411

Predicate Device for Previous Cleared Version 1.0:

IMPAC Medical Systems, Inc.

QwikSIM Virtual Simulation System, 510(k) #: K013531.

Predicate Device for Current Submitted Version 2.0:

ADAC Laboratories

Image Fusion and Review System, 510(k) #: K973233.

Device Description: The *IKOEngelo* version 2.0 device is a software system upgraded from version 1.0. This submitted new version has better contour modification tool, faster image files loading and display, and a new function for image fusion. For the same purpose of version 1.0, this software will assist radiation oncologists, with the assistance of physicists and dosimetrists, to

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more efficiently perform contour delineation of the tumor target and normal tissue on patient's CT images.

The sequence of events is illustrated in the following bullet items:

- Continuing from version 1.0 software with improved contouring tools.
- Improved image I/O performance and display.
- Multi-modality image fusion to assist contouring works.

Continuing the same workflow as version 1.0 with the followings:

- Final review and approve patient's contours by qualified radiation oncologist.
- Export patient's CT with its contours to the treatment planning system used by the facility.

Intended Use:

The *IKOEngelo* System is intended for use in tumor and normal tissue contour delineation to support the radiotherapy treatment planning process

Technological Characteristics:

The improved functions in *IKOEngelo* version 2.0 for better contouring tools and faster image I/O handling/display are maintaining the same substantially equivalence to QwikSim (IMPAC Medical Systems, Inc., K013531) as *IKOEngelo* version 1.0 (K061006).

The new added Image Fusion function in *IKOEngelo* version 2.0 and Image Fusion and Review System (ADAC Laboratories, K973233) both have same process of importing DICOM[3] images and then perform 3D image registration.

Although functionality is not identical, the use and operation of the *IKOEngelo* device is substantially equivalent to the previously cleared predicate devices and does not raise new issues of safety or effectiveness.

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Verification and Validation:

The verification and validation test procedures for *IKOEngelo* version 2.0 was developed based on IKOEtech company's standard test plans. The verification test procedures were executed and discrepancies were captured and evaluated with "criticality level", then the corresponding "correction actions" were generated.

The validation test results have demonstrated that the contour modification tools were improved with efficiency and versatility, the image file loading and display were faster and the new image fusion functions were similar to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2008

Ms. Huimin (Helen) Chao
President
IKOEtech, LLC
6223 Richmond Avenue, Suite 303
HOUSTON TX 77057

Re: K083591
Trade/Device Name: IKOEngelo™
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: KPQ
Dated: November 20, 2008
Received: December 4, 2008

Dear Ms. Chao:

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 such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number (if known): Pending K083591

Device Name: *IKOEngelo*™

Indications for Use:

The *IKOEngelo*™ System is indicated for use by radiation oncologists, medical physicists, and medical dosimetrists for tumor and normal tissue contour delineation to support the radiotherapy treatment planning process. The resulting information may then be exported to a treatment planning system for dose calculation.

Prescription Use ✓ AND/OR Over-The-Counter Use___

(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)

Colin M. Pollard (acting)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083591