DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Guangzhou Raydose Software Technology, LLC
% Mr. Dennis Dong
Sales & Marketing Director
No.850 East Dongfeng Road, Guangzhou City
Guangdong Province, Room 502, Glorious Tower
Guangzhou, 510060
P. R. CHINA

August 17, 2015

Re: K150767
Trade/Device Name: EDOSE
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 6, 2015
Received: July 10, 2015

Dear Mr. Dong:

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.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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 below.

510(k) Number *(if known)*
k150767

Device Name

EDOSE

Indications for Use *(Describe)*

EDOSE is indicated to be used as an independent quality assurance (QA) tool for the treatment planning system, to verify that the treatment plan is in fact successfully delivered to the patient. EDOSE is used by oncologist, radiotherapy physicist and/or radiotherapy dosimetrist to check the accuracy of the delivery by high energy linear accelerator that are planned to be applied or have been applied to a patient. By using the specific measuring device, the product can output the dose distribution of the patient or phantom based on treatment field image data and theoretical calculation. The product can calculate and check the dose distribution to be or has been delivered. In addition, the product may be used to display the dose distribution on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.

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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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

August 13, 2015

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor:	Guangzhou Raydose Software Technology., LLC.
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3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name:	EDOSE
Common Name:	Standalone Software Quality Control System
Classification:	Medical Charged-particle Radiation Therapy Systems
Product code:	IYE
Classification Panel:	Radiology
Device Class:	II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicates within this submission are as follows:

Math Resolutions, LLC, Dosimetry Check with Exit Dose has been cleared by FDA through 510(k) No.K101503 (Decision Date – August 04, 2010),

5. Description of the Device [21 CFR 807.92(a) (4)]

With technological development, precise radiotherapy has become the primary means of radiotherapy techniques. However, due to higher requirements that Radiation therapy technology refinement purposed, it also produced a greater risk of potential treatment failure. The greater the level of potential therapeutic accident, which makes quality assurance become a necessary step to ensure that radiotherapy can implement, but also for the quality assurance the work presents a higher demand.

EDOSE is a three-dimensional dose verification system making IMRT verification becomes accurate, efficient and fast. This system fully supports Varian and Elekta accelerators; it can verify conventional IMRT, IMRT and VMAT. With Collapsed Cone convolution algorithm, it realizes the reconstruction of the three-dimensional dose and combined with the CT image, making the three-dimensional distribution of the dose at a glance. By using CUDA parallel algorithms, EDOSE quickly and efficiently provide the entire program as well as the calculation results of individual GAMMA radiation field, and visually display GAMMA distribution. Meanwhile, EDOSE provides automatic correction of absolute dose and EPID position to support DVH comparison chart and the move of isodose curve. Through a series of powerful functions, the accelerator quality assurance has become so easy.

6. Indications for Use [21 CFR 807.92(a)(5)]

EDOSE is indicated to be used as an independent quality assurance (QA) tool for the treatment planning system, to verify that the treatment plan is in fact successfully delivered to the patient. EDOSE is used by oncologist, radiotherapy physicist and/or radiotherapy dosimetrist to check the accuracy of the delivery by high energy linear accelerator that are planned to be applied or have been applied to a patient. By using the specific measuring device, the product can output the dose distribution of the patient or phantom based on treatment field image data and theoretical calculation. The product can calculate and check the dose distribution to be or has been delivered. In addition, the product may be used to display the dose distribution on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.

7. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

7.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device EDOSE	Predicate Device Dosimetry Check with Exit Dose
1	**Intended Use**	EDOSE is indicated to be used as an independent quality assurance (QA) tool for the treatment planning system, to verify that the treatment plan is in fact successfully delivered to the patient. EDOSE is used by oncologist, radiotherapy physicist and/or radiotherapy dosimetrist to check the accuracy of the delivery by high energy linear accelerator that are planned to be applied or have been applied to a patient. By using the specific measuring device, the product can output the dose distribution of the patient or phantom based on treatment field image data and theoretical calculation. The product can calculate and check the dose distribution to be or has been delivered. In addition, the product may be used to display the dose distribution on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.	The product is to be used by radiation oncologist, dosimet-rist, and radiation therapy physicist to check the correctness of the x-ray treatment fields from high energy treatment machines that are planned to be or have been applied to a patient. This product is to be used in addition to the treatment planning system to provide a means for additional and redundant verification that the plan is in fact successfully accomplished. This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the measurement of each x-ray field and a theoretical calculation. This product does not provide any quality assurance that the fields are. in fact correctly applied to and correctly aligned with the patient anatomy a planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.

7.2 Comparison table

Table 2 General Comparison

ID	Comparison Item	Proposed Device EDOSE	Predicate Device Dosimetry Check with Exit Dose
2	**General**		
2.1	Classification Name	Quality Control for Medical Charged-particle Radiation Therapy Systems.	Quality Control for Medical Charged-particle Radiation Therapy Systems.
2.2	Product Code	IYE	IYE
2.3	Regulation Number	892.5050	892.5050
2.4	Panel	General & Plastic Surgery	General & Plastic Surgery
2.5	Class	Class II	Class II
3	**Performance**		
3.1	Pre-treatment images	Yes	Yes
3.2	Exit images	Yes	Yes
3.3	Compute dose to patient	Yes	Yes
3.4	Compare to planning system dose	Yes	Yes
3.5	Used for verifying the correctness of radiation therapy treatments	Yes	Yes
3.6	Uses a line in the transverse plane through the radiation field measurement provided to Dosimetry Check. A prior measured longitudinal profile is applied to each detector signal to complete the radiation field.	No	No
3.7	Generates a report as described in the Dosimetry Check manual using either the auto-report feature, or the user may construct their own report using the evaluate tools.	Yes	Yes
3.8	Photons (x-ray)	Yes	Yes

ID	Comparison Item	Proposed Device EDOSE	Predicate Device Dosimetry Check with Exit Dose
3.9	Electrons	No	No
3.10	Protons	No	No
3.11	Ability to use the TomoTherapy detector data measured in a pretreatment dry run without the patient and the detector data taken during treatment	No	No
3.12	Operating Systems	Microsoft Windows XP, Windows 7, Windows 8	Microsoft Windows XP, Windows Vista. Windows 7, and Ubunto 9.04 (Linux)

7.3 Discussion of Differences:

It is reasonable that there are some differences between our new device and its predicate. All of parameters comply with 21CFR1020.33 and related IEC standards. We did not use any new technology in this system, so those differences between our new system and its predicate do not affect the safety and effectiveness (SE).

Review of ID 1 - Intended use, both of them are used by oncologist, radiotherapy physicist and/or radiotherapy dosimetrist to check the accuracy of the delivery by high energy Linear accelerator that are planned to be applied or have been applied to a patient. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected

Review of ID 2 - General, both are the same, so the SE is not affected.

Review of ID 3 - Performance, both are the same, so the SE is not affected.

8. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Guangzhou Raydose Software Technology., LLC. concludes that EDOSE is substantially equivalent to predicate devices with regard to safety and effectiveness.

Since EDOSE is a software product, the software system test and the product design verification are performed as the same single testing activity. During the system test period, all of the product level and software requirements have been tested and verified.