March 13, 2018

DOSIsoft S.A.
% Mr. Luc DIOT
Quality Director
45/47, avenue Carnot
94230 Cachan
FRANCE

Re: K180106
Trade/Device Name: ThinkQA
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 29, 2017
Received: January 16, 2018

Dear Mr. Diot:

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.

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.

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

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)*
K180106

Device Name
ThinkQA

Indications for Use *(Describe)*
ThinkQA is a radiation therapy dosimetry Quality Assurance (QA) device consisting of a software framework intended to contain a suite of modules to verify that radiation dose actually delivered to the patient is as intended.

The Epibeam module contained in ThinkQA is intended to be used as follows:

Epibeam is a standalone software tool independent of the linear accelerator, the TPS and the Record-and-Verify system. It is intended to assist in reducing the clinical risk in the delivery of radiotherapy treatments and does not alter the treatment delivery. It is to be used by a radiation oncology medical professional as a guide to provide pretreatment plan delivery verification.

The software is to be used for the purposes of detecting errors in the delivery of radiation therapy prior to treatment, like corruption of the transferred plan data to the treatment unit, inappropriate multileaf collimator sequence or beam output malfunctioning. The software acquires data from the Electronic Portal Imaging Device (EPID) during a blank fraction dedicated to the pretreatment verification without the presence of the patient and subsequently processes it. The processed data is compared with data calculated by the Epibeam system. The comparison is derived on one hand, from the application of dose conversion to the EPID data and on the other hand, from the computation of a predicted dose image under ideal conditions of functioning. A gamma-index analysis is then performed according to the dose difference and distance-to-agreement criteria provided by the user.

Epibeam is not a treatment planning system and cannot be used to generate radiotherapy treatment plans. It provides an independent means of checking the reliability of the dose delivery for each beam in reference to TPS data.

Epibeam therefore provides an added level of treatment quality assurance, thus giving clinicians confidence especially when complex treatment techniques are employed (gantry-fixed and rotational intensity modulated radiation therapy).

Epibeam is intended to support decision making in relation to the delivery of treatment plan to the patient with every clinical linear accelerators equipped with an EPID, but does not alter the existing Indications for Use of the treatment unit.

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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Premarket Notification 510(k) Summary

[as required by 21 CFR 807.92]

510(k) Summary

1. Date the Summary was prepared: 2017-12-08

2. Submitter:

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Contact Name:	Mr. Marc USZYNSKI

3. Device Information:

Proprietary Name:	ThinkQA
Trade Names:	ThinkQA, EPIbeam
Common Name:	Standalone software quality control system
Classification Name:	Medical charged-particle radiation therapy system (Class II, 21 CFR 892.5050, Product Code IYE)

4. Predicate Device:

K133572 – ARIA Radiation Therapy Management - "*Enhanced Portal Dosimetry gamma evaluation*" feature – Varian Medical Systems, Inc.

Executive Summary

5. Product Description:

ThinkQA is a modular software suite composed of the module Epibeam which is a quality assurance tool dedicated to Patient Specific QA for pretreatment verification of irradiation beams.
The EPIbeam verification module integrated to the ThinkQA software platform is a Quality Assurance tool in external beam radiation therapy, used in combination with the electronic portal imaging device (EPID) and dedicated to the irradiation beam pre-treatment verifications, particularly for IMRT and VMAT techniques.

EPIbeam principle is based on the comparison of two images expressed in terms of absolute dose: on the one hand, a RT Plan defined in the TPS is used for the acquisition of a real portal image (test image) with the EPID directly irradiated (without attenuating medium); on the other hand, the same RT Plan is used to compute a theoretical portal image (reference image). Specific models and algorithms are applied to express both images in the same absolute dose terms.

The dose images obtained from the same RT Plan, one by the conversion model of the acquired raw EPID images and the other by the prediction model, can be quantitatively compared through dose difference mappings or 2D gamma-index. Both models are based on dosimetric data provided from the TPS.

6. Intended Use and User profiles:

ThinkQA is a modular software suite composed of the module EPIbeam which is a quality assurance tool dedicated to Patient Specific QA for pretreatment verification of irradiation beams.

The intended Use for the EPIbeam module contained in ThinkQA product is as follows:

> EPIbeam is a standalone software tool independent of the linear accelerator, the TPS and the Record-and-Verify system. It is intended to assist in reducing the clinical risk in the delivery of radiotherapy treatments and does not alter the treatment delivery. It is to be used by a radiation oncology medical professional as a guide to provide pretreatment plan delivery verification.

The software is to be used for the purposes of detecting errors in the delivery of radiation therapy prior to treatment, like corruption of the transferred plan data to the treatment unit, inappropriate multileaf collimator sequence or beam output malfunctioning. The software acquires data from the Electronic Portal Imaging Device (EPID) during a *blank* fraction dedicated to the pretreatment verification without the presence of the patient and subsequently processes it. The processed data is compared with data calculated by the EPIbeam system. The comparison is derived on one hand, from the application of dose conversion to the EPID data and on the other hand, from the computation of a predicted dose image under ideal conditions of functioning. A gamma-index analysis is then performed according to the dose difference and distance-to-agreement criteria provided by the user.

EPIbeam is not a treatment planning system and cannot be used to generate radiotherapy treatment plans. It provides an independent means of checking the reliability of the dose delivery for each beam in reference to TPS data.

EPIbeam therefore provides an added level of treatment quality assurance, thus giving clinicians confidence especially when complex treatment techniques are employed (gantry-fixed and rotational intensity modulated radiation therapy).

EPIbeam is intended to support decision making in relation to the delivery of treatment plan to the patient with every clinical linear accelerators equipped with an EPID, but does not alter the existing Indications for Use of the treatment unit.

7. Technological Characteristics Summary:

The detailed technological characteristics and the substantial equivalence discussion as included in the body of the 510(k) submission support the claim that ThinkQA and its EPIbeam module technological characteristics and indication for use are substantially equivalent to that of its predicate device ARIA Radiation Therapy Management – "*Enhanced Portal Dosimetry gamma evaluation*" feature – K133572.

The table below compares the device functionalities of ThinkQA / EPIbeam and Portal Dosimetry component of ARIA Radiation Therapy Management product (K133572).

Functionality	Think QA EPIbeam DOSIsoft SA (this submission)	Portal Dosimetry Varian Medical Systems
FDA Control Number	**-**	**K133572**
CE Marked	**Yes**	**Yes**
Pretreatment check	Yes	Yes
Independent software	Yes	Only compatible with Varian hardware and software
Pretreatment images	Yes	Yes
Algorithm for computing predicted reference dose image	Yes	Yes (Eclipse TPS - PDIP)
Algorithm for converting acquired portal image into dose image	Yes	Yes
Compares measured dose image to the reference dose image according to gamma-index analysis	Yes	Yes
Generates a report for the reviewer	Yes	Yes
Results include gamma agreement index per beam	Yes	Yes
Results include significant statistic gamma index values per beam	Yes	Yes
Ability to view test and reference images	Yes	Yes
Ability to view superimposed test/reference dose profiles	Yes	Yes
Ability to view 2D gamma index distribution	Yes	Yes
Patient control database	Yes	Yes (ARIA database)
User defined Alert Criteria for out of tolerance analysis	Yes	Yes

Import Approved Plan data from Treatment Planning System	Yes	Yes (ARIA database)
Import Portal Images from pretreatment fraction	Yes	Yes
Analysis performed automatically offline	Yes	Yes
Multiple treatment techniques	Static, IMRT, VMAT	IMRT, VMAT (RapidARC)
EPID panel Calibration required for commissioning	Yes	Yes
TPS results for dose data reference	Yes	Yes

The substantial equivalence discussion sustains the claim that *ThinkQA* software and its *EPIbeam* module intended use, clinical, technical (principles of operation, functionalities and critical performances) and biological characteristics are the same as for the predicate device *Portal Dosimetry* component of *ARIA Radiation Therapy Management* product CE marked and legally marketed in the U.S. (K133572).

In summary, DOSIsoft therefore considers that, in its opinion, ThinkQA / EPIbeam is substantially equivalent and is as safe and effective as the predicate device.

8. Performance Testing – Bench:

ThinkQA software was submitted to performance, functional and algorithmic testing.
The results of performance, functional and algorithmic testing demonstrate that ThinkQA meets the requirements of the device, which are demonstrated to be substantially equivalent to those of the predicate device.

ThinkQA software underwent unit, integration and system tests.
All test cases were documented with the results showing that acceptance criteria were met.

Validation of the system under clinically representative conditions has been performed. Results from verification and validation testing demonstrate that conformance to applicable technical design specification has been met and that safety and effectiveness have been achieved.

Regression testing was also successfully performed.

All product requirements can be traced to the test results.

Performance Testing Conclusions:

The conclusions of the verification and validation activities are that the safety, performances and benefit / risk ratio under normal conditions of use met device requirements.

The substantial equivalence discussion and the performance testing conclusions demonstrate that ThinkQA is substantially equivalent to and performs at least as safely and effectively as its predicate device.