June 12, 2026

DOSIsoft SA
Ahmad Khalil
Quality and Regulatory Affairs Responsible
45/47 Avenue Carnot
Cachan, 94230
France

Re: K252937
Trade/Device Name: ThinkQA 3
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: May 13, 2026
Received: May 13, 2026

Dear Ahmad Khalil:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252937

Please provide the device trade name(s).

ThinkQA 3

Please provide your Indications for Use below.

ThinkQA 3 is a software medical device designed for Patient-Specific Quality Assurance (QA) in External Beam Radiation Therapy (RT).

ThinkQA 3 is intended to help verify that each patient's treatment is delivered as planned, by identifying discrepancies between treatment plan and actual delivery.

ThinkQA 3 consists of a software platform and a suite of independent and complementary verifications. For each patient, ThinkQA 3 imports treatment plan data and treatment machine information, such as delivery logs and EPID (Electronic Portal Image Device) images. ThinkQA 3 verifications are performed either (1) pre-treatment, or (2) post-treatment with data collected during actual treatment delivery (in vivo). ThinkQA 3 is designed for integration into both standard RT and Adaptive RT (ART) workflows.

ThinkQA 3 verifications operate independently, offering distinct insights into treatment delivery quality. With these, the clinical users can better assess proper treatment course, identify possible root causes of detected errors, evaluate clinical relevance, and assist in treatment adaptation if necessary.

ThinkQA 3 is intended for use only by qualified healthcare professionals trained in radiation therapy QA procedures. ThinkQA 3 does not recommend clinical interventions, nor directly control or modify treatment delivery. All clinical decisions must be made by qualified professionals based on their judgment and full clinical context.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Premarket Notification 510(k) Summary

[as required by 21 CFR 807.92]

#K252937 510(k) Summary

1. Date the Summary was prepared: 2026-06-12

2. Contact Details

- Applicant Name: DOSIsoft SA
- Applicant Adress: 45/47 Avenue Carnot
  94230 Cachan – FRANCE
- Applicant Contact Telephone: +33 1 41 24 26 26
- Applicant Contact: Mr. Marc USZYNSKI
- Applicant Contact Email: uszynski@dosisoft.com
- Correspondent Name: DOSIsoft SA
- Correspondent Address: 45/47 Avenue Carnot
  94230 Cachan – FRANCE
- Correspondent Contact Telephone: +33 1 41 24 26 26
- Correspondent Contact: Mr. Ahmad KHALIL
- Correspondent Contact Email: regulatory@dosisoft.fr

3. Device Name

- Device Trade Name: ThinkQA 3
- Common Name: Medical charged-particle radiation therapy system
- Classification Name: Accelerator, Linear, Medical
- Regulation Number: 892.5050
- Product Code: IYE, MUJ

4. Legally Marketed Predicate Devices

Predicate #	**Predicate Trade Name (Primary Predicate is listed first)**	**Product Code**
K231573	ThinkQA (Edition 2)	IYE
Reference #	**Reference device Trade Name**	**Product Code**
K180106	ThinkQA	IYE
K112723	EPIgray	MUJ
K172534	QualiForme D LINACWATCH/LINACVIEW	IYE

Executive Summary

5. Device Description Summary

ThinkQA 3 consists of a software platform and a suite of software modules, performing various pre-treatment and in vivo verifications.

ThinkQA 3 includes:

- a software platform that collects and receives data, performs calculations, implements workflows, and stores the results in a single database.
- a web application that allows within a homogeneous look & feel to display the computed results from any compatible web browser across the institution (with access control) and pass/fail synthetic information for the active verification's.
- a set of software modules, implementing several verifications related to a patient treatment course, namely:
  - a Secondary Dose Calc verification (SDC)
  - an EPID Pre-Treatment verification (EPT)
  - a Logfiles Pre-Treatment verification (LPT)
  - a Logfiles InVivo verification (LIV)
  - an EPID InVivo verification (EIV)
- a common administration interface, implementing users settings, verification protocols, system and users logs, licensing, database management, installation & configurations settings.

ThinkQA 3 scales to offer computation capacity from small to large radiation therapy (RT) centres, and the capability to offer a single web-based interface to access all patient treatment courses and patient information from within the RT centre.

ThinkQA 3 can be used in a modular fashion, performing only a subset of available verifications, but also provide a synthetic overview of all verifications performed for a given treatment fraction and overall treatment course for a given patient.

6. Intended Use/Indications for Use

ThinkQA 3 is a software medical device designed for Patient-Specific Quality Assurance (QA) in External Beam Radiation Therapy (RT).

ThinkQA 3 is intended to help verify that each patient's treatment is delivered as planned, by identifying discrepancies between treatment plan and actual delivery.

ThinkQA 3 consists of a software platform and a suite of independent and complementary verifications. For each patient, ThinkQA 3 imports treatment plan data and treatment machine information, such as delivery logs and EPID (Electronic Portal Image Device) images. ThinkQA 3 verifications are performed either (1) pre-treatment, or (2) post-treatment with data collected during actual treatment delivery (in vivo). ThinkQA 3 is designed for integration into both standard RT and Adaptive RT (ART) workflows.

ThinkQA 3 verifications operate independently, offering distinct insights into treatment delivery quality. With these, the clinical users can better assess proper treatment course, identify possible root causes of detected errors, evaluate clinical relevance, and assist in treatment adaptation if necessary.

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7. Indication for Use Comparison

ThinkQA 3 represents substantial equivalence to ThinkQA Edition 2.
The indications for use of ThinkQA Edition 2 are encompassed within the broader indications for use of ThinkQA 3.
Specifically, ThinkQA Edition 2 is intended for secondary dose verification by independently verifying that the dose distribution calculated by a Treatment Planning System (TPS) for External Beam Radiation Therapy (EBRT) is consistent with treatment plan parameters.
ThinkQA 3 is intended to help verify that each patient's radiation treatment is delivered as planned, by identifying discrepancies between the treatment plan and actual delivery. This intended use includes secondary dose verification functionality as well as additional pretreatment and in vivo independent verification capabilities.

Both devices are software-only medical devices that receive treatment-related data, perform independent calculations and analyses, and store results within a database. ThinkQA 3 is built upon the same underlying software platform as ThinkQA Edition 2. While ThinkQA 3 incorporates additional software modules and expanded verification functionalities, these enhancements do not alter the fundamental intended purpose of independently verifying radiation therapy treatments.

8. Technological Comparison

ThinkQA 3 is a new software Edition (Edition 3), built upon successive software Editions which were individually focusing on elementary QA verifications. ThinkQA 3 brings these elementary QA verifications into a single and consistent architecture, database and system, providing to the user an overall, integrated and comprehensive dashboard of Patient-specific QA tasks.

ThinkQA 3 has the same software architecture as ThinkQA Edition 2, already prepared to integrate several verifications. ThinkQA 3 integrates the same single dose computation engine as in ThinkQA 2. This dose computation engine is used by several other verifications inside ThinkQA 3.

ThinkQA 3 integrates also capacity to read and analyze regulatory logfiles generated by the treatment machines. These logfiles are analyzed by ThinkQA 3 as additional verification using the same dose computation engine and used either in a pre-treatment configuration or during a treatment fraction.

ThinkQA 3 also runs on a different and up-to-date operating system (AlmaLinux 9) compared to ThinkQA Edition 2.

9. Non-Clinical and/or Clinical Tests Summary

ThinkQA 3 was designed and documented in accordance with the recommendations of FDA"Guidance for the Content of Premarket Submissions for Device Software Functions" for software devices requiring Enhanced Documentation.

ThinkQA 3 was submitted to performance, functional and algorithmic testing, risk management assessment, including cybersecurity and validation activities under clinically representative conditions. The results of performance, functional and algorithmic testing, risk management assessment and validation activities under clinically representative conditions demonstrate the safety and effectiveness of ThinkQA 3 in comparison to the predicate device.

ThinkQA 3 meets the requirements of the device, its user needs and intended use, which are demonstrated to be substantially equivalent to those of the predicate device ThinkQA Edition 2.

Also, ThinkQA 3 complies with applicable recommendations of the AAPM working group 219 regarding independent calculation-based dose/MU verification for IMRT (see [1]) and the AAPM Task Group Report 307: Use of EPIDs for Patient-Specific IMRT and VMAT QA. https://doi.org/10.1002/mp.16536.

The substantial equivalence discussion sustains the claim that ThinkQA 3 intended use, clinical and technical (principles of operation, functionalities and critical performances) characteristics are the same as for the predicate device ThinkQA Edition 2 legally marketed in the U.S.

The new verification implementation, included in ThinkQA 3, for EPID in vivo has been validated in terms of performance and functional point of view to its reference device EPIgray. ThinkQA 3 provides enhancements compared to EPIgray in terms of computation and usability in the classical and new adaptative radiotherapy workflows. This approach improves commissioning, usability, training requirements, administration aspects, and support & maintenance procedures for the clinical centers.

ThinkQA 3 also includes a verification based on machine delivery logfiles with a similar functional point of view to its reference device LinacWatch / Linac View. ThinkQA 3 logfiles verification has demonstrated similar error detection capabilities as described in the scientific state of the art literature.

The results of verification and validation activities demonstrate the safety and effectiveness of ThinkQA 3 in comparison to the predicate. ThinkQA 3 meets the requirements of the device, its user needs and intended use, which are demonstrated to be substantially equivalent to those of the predicate.

In summary, DOSIsoft therefore considers that, in its opinion, ThinkQA 3 is substantially equivalent to and is at least as safe and effective as the selected predicate.

10 Conclusion

The substantial equivalence discussion sustains the claim that ThinkQA 3 shares the same intended use, clinical and technical characteristics as the predicate ThinkQA Edition 2 legally marketed in the U.S. (K231573).

In conclusion, ThinkQA 3 aligns with the device requirements, user needs, and intended use, showcasing substantial equivalence to the predicate device. Differences in certain features are assessed to have either negligible impact or no significant effect on safety and effectiveness. Thus, DOSIsoft asserts that ThinkQA 3 is substantially equivalent to its predicate device.