October 24, 2019

DOSIsoft SA
% Mr. Luc Diot
Quality Director
45/47, Avenue Carnot
94230 Cachan
FRANCE

Re: K191944
Trade/Device Name: MU2net
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 10, 2019
Received: July 30, 2019

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191944

Device Name
MU2net

Indications for Use *(Describe)*
Treatment plan verification System by double Monitor Units calculation and in vivo verifications management.

MU2net is indicated for use as a quality assurance software to verify conventional and IMRT treatment plans provided by Radiotherapy Treatment Planning Systems and transferred as DICOM RT Plan data sets.

It is also indicated for use as a quality assurance software to manage in vivo measurements performed during the patient treatment fractions.

MU2net is dedicated to be used by high qualified professionals in medical oncology and/or medical physics such as Radiation-Oncologists, Medical Physicists and Technicians performing treatment planning.

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] K191944

510(k) Summary

1. Date the Summary was prepared: 2019-07-10

2. Submitter:

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Contact Name:	Mr. Marc USZYNSKI

3. Device Information:

Proprietary Name:	MU2net
Trade Names:	MU2net
Common Name:	Standalone software quality control system
Classification Name:	Medical charged-particle radiation therapy system (21 CFR 892.5050, Class II, Product Code IYE)

4. Predicate Device:

K031975 – IMSure QA Software – Standard Imaging, Inc. (Prodigm, Inc.)

Executive Summary

5. Product Description:

MU2net is a standalone software device designed to perform secondary monitor unit (MU) or dose calculation based on DICOM RT Plan data sets provided by Radiotherapy Treatment Planning Systems.

MU2net is also designed to manage in vivo measurements performed by skin dose detectors (diode in vivo dosimetry).

6. Intended Use and User profiles:

Treatment plan verification System by double Monitor Units calculation and in vivo verifications management.

MU2net is indicated for use as a quality assurance software to verify conventional and IMRT treatment plans provided by Radiotherapy Treatment Planning Systems and transferred as DICOM RT Plan data sets.

It is also indicated for use as a quality assurance software to manage in vivo measurements performed during the patient treatment fractions.

MU2net is dedicated to be used by high qualified professionals in medical oncology and/or medical physics such as Radiation-Oncologists, Medical Physicists and Technicians performing treatment planning.

7. Technological Characteristics:

The table below compares the technological characteristics and the features of MU2net and its predicate IMSure QA Software.

Device name	**(this submission)**	**IMSure QA Software (predicate)**
510(k) number	This filing	K031975
Company	DOSIsoft SA	Standard Imaging, Inc. (Prodigm, Inc.)
Intended use	is intended to be used as a quality assurance software for secondary monitor-unit (MU) or secondary dose computations from DICOM RT Plans provided by TPS. It is also intended for in vivo dose measurements management.	Independent dose and fluence map verification software for Intensity Modulated Radiation Therapy based on Linear accelerator plans containing multi-leaf collimator leaf sequence data and fluence maps from primary IMRT treatment planning systems. Independent dose computation software for standard, simple geometry radiation therapy treatment planning and verification of monitor units based on Linear Accelerator parameters and physician prescribed dose information.
Indication for use	is indicated for use as a quality assurance software to verify conventional and IMRT (static or rotational) treatment plans provided by Radiotherapy Treatment Planning Systems and transferred as DICOM RT Plan data sets. It is also indicated for use as a quality assurance software to manage in vivo measurements performed during patient treatment fraction.	IMSure is indicated for use as a quality assurance tool to verify IMRT treatment plans developed on any radiation therapy treatment planning system with the appropriate transfer format. IMSure will also perform primary monitor unit calculations from measured physics data for plans of known geometry.
Target population	is used to validate a plan for any population (child, adult and elderly people) having a diagnosed cancer and following an External Beam Radiotherapy.	Same
Anatomical sites	is used for human medical field. is used to validate a plan for any tumor sites.	Same
Where used	is installed in medical facilities.	Same
Human factors	It is used by qualified users such as radiation oncologists, medical physicists and medical dosimetrists.	Same
Design	Dose computations are performed at local workstation. Multiple simultaneous dose calculations.	Same
Performances		
Algorithm – map verification	No	Single Source model
Dose / MU calculation Algorithm	Commissioning based on formalism booklet3 – Monitor Unit Calculation for High Energy Photon Beams from ESTRO and Report 12 from Netherlands Commission on Radiation Dosimetry (NCS). Inspired from J. H. Kung and al. “A monitor unit verification calculation in intensity modulated radiotherapy as a dosimetry quality assurance” Medical	3DCRT: Khan (classical) IMRT/VMAT: Single Source model, Clarkson scatter algorithm based on Stanford University method

Device name	(this submission)	IMSure QA Software (predicate)
	Physics 2000 October; 27(10):2226-30.	
Patient Geometry Specifications	Dose computing: Large parallelepipedic water phantom. Calculation point position and depth: external/internal/support outlines and electron density from DICOM RT StructureSet for VMAT plans	Two dimensional, graphical user interface based
Machines supported	Commercially available Linear Accelerators . Supports MR-Linacs.	Commercially available Linear Accelerators.
Calculation point for MU calculations	Off-Axis and depth specified distances required for dose calculation (dose point coordinates) using measured physical beam data. Dose verification is performed using a list of points of interest given in the RT Plan file.	Same
Physics Data	Measured, tabular database stored.	Measured, tabular database stored, multiple linear allowed.
Scatter table	Processed	Measured.
Import plan data	DICOM RT	DICOM RT RTP link
Supported treatment technics	3D CRT, IMRT, VMAT	Same
TPS supported	– DOSIsoft/Isogray, – Varian/Eclipse, – Philips/Pinnacle, – Elekta/Xio, Monaco – Nucletron/Oncentra – RaySearch/RayStation	Same
Database	Provides easy access to patient information allowing you to verify, change calculations or change the status of the plan. Gives multiple user access to all patient calculation information using a web-based interface.	Provides easy access to patient information allowing you to verify, change or copy calculations. Gives multiple user access to all patient calculation information from a network server.
Import in vivo dose data	Automatic or manual import of detector measurements.	The software allows a simple interface to enter the collected data and computes the expected diode reading for each treatment field.
Dose calibration method(s)	Apply to all beams with isocentric or fixed SSD calibration	Isocentric or fixed SSD calibration distance.
Export data	Results can be printed out or saved as Portable Document Format (PDF) files. The original DICOM RT Plan provided by the TPS is never modified and can be forwarded to the R&V system.	Paper documentation DICOM RT RTP Link
Cybersecurity	Secure login with layered authorization model.	Secure login with layered authorization model.
Traceability	The user can see the chronological account of events from the file import to the current status.	Not available
Review interface	Web based interface	Windows based interface
Operating system	Linux operating system	Microsoft Windows operating system

8. Performance Testing – Bench:

MU2net was designed and documented in accordance with the recommandations of FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” for software devices identified as Major Level of Concern.

MU2net was submitted to performance, functional and algorithmic testing, risk management assessment 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 MU2net.

MU2net 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.

9. Conclusions

The substantial equivalence discussion sustains the claim that MU2net intended use, clinical and technical (principles of operation, functionalities and critical performances) characteristics are the same as for the predicate device IMSure QA Software legally marketed in the U.S. (K031975).
The differences on some functional features do not significantly affect, or may not significantly affect, safety or effectiveness.

The results of verification and validation activities demonstrate the safety and effectiveness of MU2net.
MU2net 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.

In summary, DOSIsoft therefore considers that, in its opinion, MU2net is substantially equivalent to and is at least as safe and effective as the predicate device.