



QualiFormeD Sarl
% Mr. Thomas Kroenke
Principal Consultant
Speak To Market, Inc.
PO Box 3018
NEDERLAND CO 80466

October 27, 2017

Re: K172534

Trade/Device Name: QualiFormeD Sarl LINACwatch/LinacView
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 21, 2017
Received: August 22, 2017

Dear Mr. Kroenke:

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 (DICE) 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 (DICE) 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172534

Device Name

QualiFormeD Sarl LINACwatch/LinacView

Indications for Use (Describe)

QualiFormeD LINACWATCH / LINACVIEW is stand-alone software that analyzes radiation therapy machine (linear accelerator) performance for each fraction automatically using log files provided by the radiation therapy machine. It is to be used by trained radiation oncology personnel as a guide to alert this professional to potential machine delivery issues that can affect treatment quality and workflow.

QualiFormeD LINACWATCH / LINACVIEW is not primary treatment planning or 3D dose calculation software, and cannot be used to generate radiotherapy treatment plans.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(k) Summary

510(k) Summary
provided in accordance with 21 CFR §807.92(C)

Submission Date: 21 August 2017

Submitter: QualiFormeD Sarl
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Manufacturing Site: QualiFormeD Sarl
 14 rue de la Vieille Horloge
 85000 La Roche Sur Yon, France

Trade Name: QualiFormeD LINACWATCH / LINACVIEW

Classification Name: Accelerator, Linear, Medical

Classification Regulation: 21 CFR §892.5050

Product Code: IYE

Substantially Equivalent Devices:	<i>New QualiFormeD Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
	QualiFormeD LINACWATCH / LINACVIEW	K140660	Mobius Medical Systems Mobius3D
		K141800	Sun Nuclear Corporation Model 1215 PerFRACTION

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Device Description: QualiFormeD LINACWATCH / LINACVIEW is a standalone software product analyzes logfiles generated by Varian and Elekta linear accelerators during radiation treatments. Logfile analysis can be with respect to the “prescription” DICOM radiotherapy (RT) Plan or with respect to the first logfile in a series of logfiles for each treatment and each beam. Initial logfiles that may be created for pre-treatment intensity-modulated radiation therapy (IMRT) quality assurance (QA) can be excluded from treatment session analysis.

The preferred method of running QualiFormeD LINACWATCH / LINACVIEW is in “batch” mode. In this mode, QualiFormeD LINACWATCH / LINACVIEW automatically processes logfiles and analyzes them, sending emails to designated staff for non-compliant results over an internet connection.

QualiFormeD LINACWATCH / LINACVIEW allows the user to verify for every treatment, in real time, with email notifications on alert or failure, the following parameters:

- The position of each moving multi-leaf collimator (MLC) leaf;
- The position of MLC carriages and jaws;
- The percentage of monitor units (MUs) delivered;
- The gantry rotation angle;
- The collimator rotation angle;
- The beam on/off statistics; and
- The reconstructed integrated fluence.

Additionally, after any number of treatments has been analyzed, QualiFormeD LINACWATCH / LINACVIEW allows the user to create RT Plans that can simulate the composite behavior of the analyzed logfiles. These RT Plans can be imported into the treatment planning system (TPS) to compare intended doses with those actually delivered, although this estimated dose does not include dosimetric changes due to patient setup or geometric changes. Adobe Acrobat® PDF reports documenting machine performance can be created at any point during treatment.

At the end of a course of treatment when the treatment series is closed, a composite RT Plan is automatically created that summarizes the composite behavior of all analyzed logfiles as well as two (2) final reports, a short and a comprehensive report, that documents all aspects of the treatment course.

Step and Shoot, Sliding Window, and Volumetric Modulated Arc Therapy (VMAT) IMRT techniques are supported.

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Intended Use:

QualiFormeD LINACWATCH / LINACVIEW is stand-alone software that analyzes radiation therapy machine (linear accelerator) performance for each fraction automatically using log files provided by the radiation therapy machine. It is to be used by trained radiation oncology personnel as a guide to alert this professional to potential machine delivery issues that can affect treatment quality and workflow.

QualiFormeD LINACWATCH / LINACVIEW is not primary treatment planning or 3D dose calculation software, and cannot be used to generate radiotherapy treatment plans.

Technology Comparison:

QualiFormeD LINACWATCH / LINACVIEW employs the same technological characteristics as the predicate device.

<i>Characteristic</i>	<i>Mobius Medical Systems Mobius3D plus FX (K140660)</i>	<i>Sun Nuclear PerFraction (K141800)</i>	<i>QualiFormeD LINACWATCH / LINACVIEW</i>
<i>Desktop software</i>	Mobius3D: Yes MobiusFX: No	No	Yes
<i>IMRT/VMAT Analysis</i>	Mobius3D: Yes MobiusFX: Yes	Yes	Yes
<i>Logfile-based analysis</i>	Mobius3D: Yes MobiusFX: Yes	No	Yes
<i>All fractions analyzed</i>	Mobius3D: No MobiusFX: No	Yes	Yes
<i>Analysis in real-time</i>	Mobius3D: No MobiusFX: No	No	Yes
<i>Automatic process</i>	Mobius3D: Yes MobiusFX: No	Yes	Yes
<i>Dashboard results for therapists</i>	Mobius3D: No MobiusFX: No	No	Yes
<i>Dashboard results for physicists</i>	Mobius3D: Yes MobiusFX: Yes	Yes	Yes

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Summary of Performance Testing:

Software

QualiFormeD LINACWATCH / LINACVIEW contains MODERATE level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*
- *FDA guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicated that QualiFormeD LINACWATCH / LINACVIEW complies with predetermined specifications and the applicable standard.

Performance Testing – Bench

QualiFormeD LINACWATCH / LINACVIEW was tested in accordance with internal specifications:

Test results indicated that QualiFormeD LINACWATCH / LINACVIEW complies with predetermined specifications.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of QualiFormeD LINACWATCH / LINACVIEW. The results of these activities demonstrate that QualiFormeD LINACWATCH / LINACVIEW is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, QualiFormeD LINACWATCH / LINACVIEW is considered substantially equivalent to the predicate device.