



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

Radformation
% Mr. Parul Chansoria
Regulatory Consultant
Elexes
6494 Tralee Village Drive
DR DUBLIN CA 94568

December 1, 2016

Re: K162468
Trade/Device Name: ClearCheck
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 28, 2016
Received: October 28, 2016

Dear Mr. Chansoria:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a faint, large watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K162468

Device Name

ClearCheck

Indications for Use (Describe)

ClearCheck is intended for quality assessment of 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Section 5. 510(k) Summary

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

5.1 Submitter's Information

Table 1 : Submitter's Information	
Submitter's Name:	Kurt Sysock
Company:	Radformation, LLC
Address:	429 East 52nd Street, Unit 4G, New York, NY 10022
Contact Person:	Parul Chansoria Founder, Elexes
Phone:	650-528-2445
Fax:	-----
Email:	parul@elexes.com
Date of Summary Preparation:	August 24 th , 2016

5.2 Device Information

Table 2 : Device Information	
Trade Name:	ClearCheck
Common Name:	Oncology Information System
Classification Name:	Class II
Classification	Medical charged-particle radiation therapy system, dosimetric quality control system
Regulation Number:	892.5050
Product Code:	IYE
Classification Panel:	Radiology

5.3 Predicate Device Information

Model 1216 Quality Reports (K142142)

5.4 Device Description

The ClearCheck device (model RADCC) is a software intended to present treatment plans obtained from Eclipse Treatment Planning System (also referred to as Eclipse TPS) of Varian Medical Systems in a user friendly way (numerical form of data) for user approval of the treatment plan. ClearCheck runs as a dynamic link library (dll) plugin to Varian Eclipse.

It is designed to run on the Windows Operating System and generated reports can be viewed on Internet Explorer. ClearCheck performs calculations on the plan obtained from Eclipse TPS (Version 12 (K131891) and Version 13.5 (K141283)) which is a software used by trained medical professionals to design and simulate radiation therapy treatments for malignant or benign diseases.

ClearCheck has two components:

1. A standalone Windows Operating System executable application that is used for administrative operations to set specified default settings and user settings.
2. A plan evaluation application that is a dynamic link library (dll) file that is a plugin to the Varian Medical Systems Eclipse TPS. The plugin is designed to evaluate the quality of an Eclipse treatment plan. Plan quality is based on user specified **Dose Constraints** and **Plan Check Parameters**.

5.5 Indications for Use

ClearCheck is intended for quality assessment of radiotherapy treatment plans

5.6 Technological Characteristics

The ClearCheck (Subject Device) makes use of a Predicate Device, the Model 1216 Quality Reports (142142).

5.6.1 ClearCheck vs. Model 1216 Quality Reports (K142142)

Table 3 : Substantial Equivalence Table for ClearCheck			
Parameters	Subject Device: ClearCheck Radformation	Predicate Device: Model 1216 Quality Reports Sun Nuclear Corporation (K142142)	Equivalence
Indications for use	ClearCheck is intended for quality assessment of radiotherapy treatment plans	Model 1216 Quality Reports is intended for quality assessment of radiotherapy treatment plans and the radiotherapy treatment planning process.	Equivalent
Pure Software Device	Yes	Yes	Equivalent
Intended users	Medical physicists, medical dosimetrists, and radiation oncologists	Medical physicists, medical dosimetrists, and radiation oncologists	Equivalent
OTC/Rx	Rx	Rx	Equivalent

Table 3 : Substantial Equivalence Table for ClearCheck

Parameters	Subject Device: ClearCheck Radformation	Predicate Device: Model 1216 Quality Reports Sun Nuclear Corporation (K142142)	Equivalence
	ClearCheck software runs on a standard PC running a Windows Operating System (OS). The software holds all vital data in memory during each analysis and report generation session.	Model 1216 Quality Reports software runs on a standard PC running a Windows Operating System (OS). The software holds all vital data in memory during each analysis and report generation session.	Equivalent
Operating System	Windows 7 (32- or 64-bit), Windows 8 (32- or 64-bit), Windows 10 (32- or 64-bit), Windows Server 2008, 2008 RS, and 2012.	Windows 7 (32- or 64-bit), Windows 8 (32- or 64- bit), and Windows Server 2008, 2008 R2, and 2012.	Equivalent
CPU	2.4+ GHz and Multi-core processors (2+ cores, 4+ threads)	2.4+ GHz and Multi-core processors (2+ cores, 4+ threads)	Equivalent
Hard Drive Space	Software components fully installed require only ~3.5MB, but storage requirement for patient data are much larger and vary from clinic-to-clinic. A minimum of 100 GB hard drive is suggested for larger patient template sets.	Software components fully installed require ~20 MB, but storage requirements for patient data and archives are much larger but will vary clinic-to-clinic. A minimum of 900 GB hard drive is suggested with larger drives for DICOM archives.	Differ
Display Resolution and Color Depth	1280 x 1024, 24- or 32- bit color depth.	1920 x 1080 screen resolution, 24- or 32-bit color depth.	Differ

5.6.2 Similarities

- The intended use is same for the Subject and the Predicate Device.
- Both the Predicate and the Subject Devices are pure software devices meant for prescription use
- The Subject and the Predicate Devices are classified under the Product Code IYE and the common name “oncology information system”
- The intended user of the Subject Device is the same as the Predicate Device
- The Subject and Predicate Devices require similar processors and operating systems. However, ClearCheck is supported by an additional Operating System Windows 10 (32- Or 64-bit)
- Both Subject and Predicate Devices run on a standard PC with a Windows Operating System (OS). The software devices hold all vital data in memory during each analysis and report generation session.

5.6.3 Differences

- The install size of the Subject Device is only ~3.5MB whereas the install size of the Predicate Device is 20 MB of storage requirement. ClearCheck recommends 100GB of storage space and Predicate Device recommends 900GB of storage space. This is because ClearCheck only saves constraint templates whereas Model 1216 Quality Reports stores DICOM datasets which are much larger when compared to constraint template files. Thus, ClearCheck requires much less storage. However, these differences don't raise any new questions for safety and effectiveness of the Subject Device w.r.t. the Predicate Device.
- The color depth for both the Predicate and Subject Devices are the same. The resolution required for the Subject Device (1280x1024: D-VHS, HD DVD, Blu-ray, HDV (miniDV)), and the Predicate Device (1920x1080: HDV (miniDV), AVCHD, HD DVD, Blu-ray, HDCAM SR) are different. The Subject Device ClearCheck can work with the small size monitors without any impact on the image quality (1280 x 1024). Hence, this difference doesn't raise any new questions for safety and effectiveness of the Subject Device w.r.t. the Predicate Device.

5.7 Performance Data

As with the Predicate Device, no clinical trials were performed for ClearCheck. Verification tests were performed to ensure that the software works as intended and pass/fail criteria were used to verify requirements.

5.8 Conclusion

ClearCheck is deemed substantially equivalent to the Predicate Device, Model 1216 Quality Reports (K142142) due to the similarities in intended use and function. Verification and Validation testing and Hazard Analysis demonstrate that ClearCheck is as safe and effective as the Predicate Device. The minor technological differences between ClearCheck and the Predicate Device do not raise any questions on the safety and effectiveness of the Subject Device.