Sun Nuclear Corporation
% Ms. Rene' Hardee
Regulatory Affairs Specialist III
3275 Suntree Blvd.
MELBOURNE FL 32940

October 25, 2017

Re: K170307
Trade/Device Name: SunCHECK
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 13, 2017
Received: October 16, 2017

Dear Ms. Hardee:

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,

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)*
K170307

Device Name
SunCHECK

Indications for Use *(Describe)*
SunCHECK is a software platform intended to collect, detect, compare, calculate, analyze, display, and store radiotherapy quality assurance and dosimetry data.

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.

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:

Department of Health and Human Services
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Office of Chief Information Officer
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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."

510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

September 27, 2017

Submitted by:

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Rene' Hardee
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Classification Name:

Accelerator, Linear, Medical

Common Name:

Secondary check QA software

Proprietary Names:

Model 1299028 SunCHECK

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Accelerator, Linear, Medical
Product code: IYE

Class II

Predicate Devices:

Primary Predicate:

1. Model Name: PerFRACTION
   Common Name: Secondary check QA software
   510(k) # K141800
   Manufacturer: Sun Nuclear Corporation
   Submitted: July 03, 2014

   To our knowledge, this predicate has not been subject to a design-related recall.

Reference Device:

2. Model Name: DoseCHECK
   Common Name: Secondary check QA software
   510(k) # K161946
   Manufacturer: Sun Nuclear Corporation
   Submitted: July 15, 2016

   To our knowledge, this predicate has not been subject to a design-related recall.

2 Description and Use:

SunCHECK is a server-based Web application which is accessible from any networked PC. It is intended to provide radiation therapy professionals with a platform that integrates patient QA, machine QA and data management workflows. This platform consists of a single GUI and database that is intended to provide a centralized view of a radiation therapy department's QA efforts.

3 Intended Use Statement:

SunCHECK is a software platform intended to collect, detect, compare, calculate, analyze, display, and store radiotherapy quality assurance and dosimetry data.

4 Technological Characteristics

The primary technological characteristics of the Model 1299028 SunCHECK can be broken up into 4 modules of functionality:

Primary Software Technological Characteristics
1. Utilization of the beam output from imaging systems including electronic portal imaging device (EPID), kV and Cone Beam CT that are part of the treatment delivery device to perform standardized QA of the treatment delivery device and associated imaging systems.
2. The usage of three dimensional volumetric imaging information and beam intensity values in DICOM-RT format to compute a dose volume (also in DICOM-RT format) and a comparison of this independent calculation to the TPS dose distribution.
3. Utilization of the beam output from an electronic portal imaging device (EPID) that is part of the treatment delivery device to perform a consistency check between fraction delivery.
4. Data storage and display.

These technological characteristics are believed to be substantially equivalent to the predicate devices as seen in the below table.

Areas of Comparison	Subject Device: Sun Nuclear Model 1299028 SunCHECK	Primary Predicate Device: Sun Nuclear PerFRACTION (K141800)	Reference Predicate Device: Sun Nuclear DoseCHECK (K161946)	Similarities and Differences
Technology	The primary technological characteristics of the Model 1299028 SunCHECK are: • PerFRACTION Technology • DoseCHECK Technology • SNC Machine Technology • Data Storage • Data Display Application Server: • Dual Intel Xeon Processor 2.4 GHz (6 Cores each with hyperthreading) • 64 GB (8x8 GB) 2133 MHz DDR4 RDIMM • Dual NVidia Quadro M4000 8GB • OS: 200 GB minimum usable free space • Recommendation for Data Drive: 5.76 TB minimum RAID 5e • Minimum 1 GB/s Ethernet with teaming considered • Microsoft Windows Server 2012 R3 Client Machine: • Google Chrome browser (recommended) or Internet Explorer 11.0 (depending upon the computer's operating system) • Pentium 4 Dual Core • CPU Speed: 1.6 GHz • Total RAM: 2 GB • Display resolution: 1280 x 1024 • Color depth: 32-bit • Minimum Windows 7 OS	The primary technological characteristics of PerFRACTION are: • The usage of EPID data to perform an independent secondary calculation. • Comparison of the calculation to the TPS calculated data. Application Server: • Dual Intel Xeon Processor 2.4 GHz (6 Cores each with hyperthreading) • 64 GB (8x8 GB) 2133 MHz DDR4 RDIMM • Dual NVidia Quadro M4000 8GB • OS: 200 GB minimum usable free space • Recommendation for Data Drive: 5.76 TB minimum RAID 5e • Minimum 1 GB/s Ethernet with teaming considered • Microsoft Windows Server 2012 R3 Client Machine: • Google Chrome browser (recommended) or Internet Explorer 11.0 (depending upon the computer's operating system) • Pentium 4 Dual Core • CPU Speed: 1.6 GHz • Total RAM: 2 GB • Display resolution: 1280 x 1024 • Color depth: 32-bit • Minimum Windows 7 OS	The primary technological characteristics of DoseCHECK are: • the usage of three dimensional volumetric imaging information and beam intensity values in DICOM-RT format to compute a dose volume (also in DICOM-RT format) • to support electron point dose calculations Application Server: • Dual Intel Xeon Processor 2.4 GHz (6 Cores each with hyperthreading) • 64 GB (8x8 GB) 2133 MHz DDR4 RDIMM • Dual NVidia Quadro M4000 8GB • OS: 200 GB minimum usable free space • Recommendation for Data Drive: 5.76 TB minimum RAID 5e • Minimum 1 GB/s Ethernet with teaming considered • Microsoft Windows Server 2012 R3 Client Machine: • Google Chrome browser (recommended) or Internet Explorer 11.0 (depending upon the computer's operating system). • Pentium 4 Dual Core • CPU Speed: 1.6 GHz • Total RAM: 2 GB • Display resolution: 1280 x 1024 • Color depth: 32-bit • Minimum Windows 7 OS	**Similarities** The SunCHECK Technology encompasses both the PerFRACTION and DoseCHECK Technologies. **Differences** SunCHECK includes the additional technology of Class I listed SNC Machine and data storage and display.

5 Performance Data and Comparison with Predicate

Model 1299028 SunCHECK has been tested using appropriate bench testing methods. Test results of the modified device have demonstrated that the device performs within its design specifications and equivalently to the predicate devices.

6 Summary

Model 1299028 SunCHECK is believed to be substantially equivalent to the predicate devices due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate that Model 1299028 SunCHECK is as safe, as effective, and performs as well as the predicate devices.