DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 16, 2016

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

Re: K161946
Trade/Device Name: Model 1217028 DoseCHECK
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 8, 2016
Received: July 15, 2016

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 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,

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)*
K161946

Device Name

Model 1217028 DoseCHECK

Indications for Use *(Describe)*

Sun Nuclear's DoseCHECK is a software product intended to independently calculate radiotherapy dose to provide a quality check of the planned dose.

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.

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Section 5 – 510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

June 10, 2016

Submitted by:

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Contact Person:

Rene' Hardee
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Ph: 321-259-6862 extension 2304

Classification Name:

Accelerator, Linear, Medical

Common Name:

Secondary check QA software

Proprietary Names:

Model 1217028 DoseCHECK

Establishment Registration Number:

1038814

Classification:

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

Class II

Predicate Device(s):

Model Name:	Mobius3D
Common Name:	Secondary check QA software
510(k) #	K140660
Manufacturer:	Mobius Medical Systems, LP
Submitted:	May 05, 2014

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

2 Description and Use:

DoseCHECK provides the clinician with the opportunity to compute dose using a different algorithm from that used by their treatment planning system (TPS). DoseCHECK utilizes the DICOM RT Plan, RT Structure Set, and CT Image Set from the TPS as inputs for the calculation, along with a linear accelerator characterization and CT-to-ED curve. The resulting dose distribution can be compared to the TPS dose distribution as a means of independent check. This comparison allows for detection of errors or inaccuracies that may occur within the TPS such as with beam modeling, calculation algorithm, and inhomogeneities.

3 Intended Use Statement:

Sun Nuclear's DoseCHECK is a software product intended to independently calculate radiotherapy dose to provide a quality check of the planned dose.

4 Technological Characteristics

The primary technological characteristics of the Model 1217028 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) and a comparison of this independent calculation to the TPS dose distribution. The technological characteristics are believed to be substantially equivalent to the predicate device.

5 Performance Data and Comparison with Predicate

Model 1217028 DoseCHECK 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 device.

6 Summary

Model 1217028 DoseCHECK is believed to be substantially equivalent to the predicate Mobius3D device due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate that Model 1217028 DoseCHECK is as safe, as effective, and performs as well as the predicate device.