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

May 13, 2016

Sun Nuclear Corporation
% Mr. James Luker
Regulatory Affairs Manager
3275 Suntree Blvd.
MELBOURNE FL 32940

Re: K160057
Trade/Device Name: ArcCHECK-MR
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 15, 2016
Received: April 19, 2016

Dear Mr. Luker:

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)*

K160057

Device Name
Model 1220-MR ArcCHECK-MR

Indications for Use *(Describe)*

Model 1220-MR ArcCHECK-MR is a three-dimensional (3D) ionizing radiation measurement device intended for radiotherapy quality assurance.

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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510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

March 25, 2016

Submitted by:

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Contact Person:

James Luker
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Ph: 321-259-6862 extension 2428

Common Name:

Dosimetric Quality Assurance for Patient Specific Radiation Treatment

Proprietary Names:

Model 1220-MR ArcCHECK-MR

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Medical charged-particle radiation therapy system
Product code: IYE

Class II

Predicate Device(s):

Model Name:	Model 1220 ArcCHECK
Common Name:	Dosimetric Quality Assurance for Patient Specific Radiation Treatment
510(k) #	K142617 (primary predicate), K131466
Manufacturer:	Sun Nuclear Corporation.
Submitted:	September 16, 2014, May 21, 2013

The predicate devices have not been subject to a design-related recall.

2 Description and Use:

Model 1220-MR ArcCHECK-MR is a three dimensional diode sensor used for ionizing radiation measurement for radiotherapy quality assurance. The cylindrical diode array is embedded in a cylindrical plastic phantom that allows for dosimetry measurements to be made from all gantry angles as the therapy beam rotates about the diode array.

The provided GUI 'SNC Patient' software application installed on the user's computer and connected to the Model 1220-MR ArcCHECK-MR by an 8 pin DIN cable and is unchanged from the K142617 predicate device.

This submission introduces Model 1220-MR ArcCHECK-MR. This model is equivalent in form and function to the cleared Model 1220, but has been verified as an MR-conditional product.

3 Intended Use Statement:

Model 1220-MR ArcCHECK-MR is a three-dimensional (3D) ionizing radiation measurement device intended for radiotherapy quality assurance.

4 Technological Characteristics

The following table provides a comparison between Model 1220-MR ArcCHECK-MR and the predicate Model 1220 ArcCHECK device.

1220-MR ArcCHECK MR (subject device)	1220 ArcCHECK (predicate device)	Comparison
The primary technological characteristics of model 1220-MR ArcCHECK-MR is the high spatial resolution of the diode detector with an array size and a detector density that enables measurement of dose distributions that have high dose gradients found in radiotherapy deliveries.	The primary technological characteristics of model 1220 ArcCHECK is the high spatial resolution of the diode detector with an array size and a detector density that enables measurement of dose distributions that have high dose gradients found in radiotherapy deliveries.	Both the subject device and predicate device have the same primary technological characteristics.
Model 1220-MR ArcCHECK-MR is an MR Conditional device.	Model 1220 ArcCHECK is an MR unsafe device.	The subject device has been designed and tested for conditional use in an MR environment. Each model will be labeled appropriately for its use environment.
Model 1220-MR ArcCHECK-MR serves as a 3D Phantom.	Model 1220 ArcCHECK serves as a 3D Phantom	Both the subject device and predicate device serve as 3D Phantoms
Hardware/software platform- Industry Standard personal computer hardware and Windows based software	Hardware/software platform- Industry Standard personal computer hardware and Windows based software	Both the subject device and predicate device use Industry Standard personal computer hardware and Windows based software
Materials PMMA cylinder with printed circuit boards. Use of stainless steel hardware.	Materials PMMA cylinder with printed circuit boards. Use of some carbon steel hardware.	The subject device utilizes Stainless steel in an attempt to minimize the potential magnetic attraction properties

5 Performance Data and Comparison with Predicate

Model 1220-MR ArcCHECK-MR 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 K142617 Model 1220 ArcCHECK device.

6 Summary

Model 1220-MR ArcCHECK-MR is believed to be substantially equivalent to the predicate ArcCHECK device due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate that Model 1220-MR ArcCHECK-MR is as safe, as effective, and performs as well as the K142617 predicate device. The changes to the predicate device described within this submission are not thought to not raise new types of safety or effectiveness questions.