



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

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

May 20, 2015

Re: K150848  
Trade/Device Name: Model 1218028 Dose Calculator  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: March 13, 2015  
Received: March 31, 2015

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,

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

For

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

Enclosure

## Indications for Use Form

**510(k) Number (if known):** K150848

**Device Name:** Model 1218028 Dose Calculator

### Indications for Use:

The Sun Nuclear Dose Calculator is a software product intended to compute a radiotherapy dose volume.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

\_\_\_\_\_  
Division Sign-Off  
Office of In Vitro Diagnostics and Radiological Health

510(k) K150848

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## Section 5 – 510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

### 1 General Provisions

Date Prepared:

March 12, 2015

Submitted by:

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Classification Name:

Accelerator, Linear, Medical

Common Name:

Secondary check QA software

Proprietary Names:

Model 1218028 Dose Calculator

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: Mobius 3D  
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:**

Model 1218028 Dose Calculator computes a dose volume for a user-specified treatment delivery device based on user-provided three dimensional volumetric imaging information (e.g., computed tomography) and beam intensity values. Both the imaging data and beam intensity values are specified in DICOM-RT format. The beam model for the specified treatment delivery device is provided with the software. The output of the SDC is a DICOM RT dose volume.

The Dose Calculator is for use with external beam photon radiation therapy calculations. Charged particle radiotherapy calculations (including electron, proton, and heavy ion therapy) are not indicated for use with this product.

The Dose Calculator software application is considered to be a software module that may be used by several Sun Nuclear Corporation products and/or 3<sup>rd</sup> party applications.

## **3 Intended Use Statement:**

The Sun Nuclear Dose Calculator is a software product intended to compute a radiotherapy dose volume.

## **4 Technological Characteristics**

The primary technological characteristics of the Model 1218028 Dose Calculator 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). The technological characteristics are believed to be substantially equivalent to the predicate device.

## **5 Performance Data and Comparison with Predicate**

Model 1218028 Dose Calculator 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 1218028 Dose Calculator is believed to be substantially equivalent to the predicate Mobius 3D device due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate that Model 1218028 Dose Calculator is as safe, as effective, and performs as well as the predicate device.