



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

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

September 11, 2015

Re: K152303  
Trade/Device Name: CT Sim Laser Alignment System  
Regulation Number: 21 CFR 892.5780  
Regulation Name: Light beam patient position indicator  
Regulatory Class: II  
Product Code: IWE  
Dated: August 14, 2015  
Received: August 14, 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,

 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)

K152303

Device Name

CT Sim Laser Alignment System

Indications for Use (Describe)

The CT Sim Laser System is used in the simulation stage of radiation therapy to prepare a patient for treatment. The lasers can be moved to a point that defines the isocenter in the CT suite. The Gammex CT Sim is intended to read laser positioning coordinates in a Gammex specified software format from a file in a shared folder. Typically the coordinates were calculated by a Radiation Therapy Treatment Planning System (RTPS) using CT images and sent to the Hospital Information System (HIS), Oncology System (OIS) or other system, by the RTPS.

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:

August 27, 2015

Submitted by:

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[KRW@Gammex.com](mailto:KRW@Gammex.com)  
Phone: 608 828 7276

Classification Name:

Light beam patient position indicator

Common Name:

Laser alignment system

Proprietary Names:

CT Sim Laser System

Establishment Registration Number:

2181970

Classification:

Regulation Number: 21 CFR 892.5780  
Name: Light beam patient position indicator  
Product code: IWE  
Class 2

Predicate Device(s):

Model Name: Philips Laser Alignment Tool  
Common Name: Laser alignment system  
510(k) #: K943381  
Manufacturer: Philips Medical Systems  
Submitted: July 13, 1994

Model Name: Centralite  
Common Name: Laser alignment system  
510(k) #: K872489  
Manufacturer: Diacor Inc.  
Submitted: June 23, 1987

To our knowledge, these predicate devices have not been subject to a design-related recall.

## **2 Description and Use:**

The CT Sim Laser System allows the radiation oncologist, medical physicist and oncology technician to precisely mark a patient for radiation therapy. CT Sim provides the ability to move the lasers to particular coordinates for alignment/marking purposes on the patient. The coordinates that the lasers are to move to may be manually input through the software graphical user interface (GUI) or through a data file with a specific format (or DICOM). CT Sim is in no way integrated with the third party Radiation Therapy Treatment Planning System (RTPS) or imaging/radiological device.

## **3 Intended Use Statement:**

The CT Sim Laser System is used in the simulation stage of radiation therapy to prepare a patient for treatment. The lasers can be moved to a point that defines the isocenter in the CT suite. The Gammex CT Sim is intended to read laser positioning coordinates in a Gammex specified software format from a file in a shared folder. Typically the coordinates were calculated by a Radiation Therapy Treatment Planning System (RTPS) using CT images and sent to the Hospital Information System (HIS), Oncology System (OIS) or other system, by the RTPS.

## **4 Technological Characteristics**

The primary technological characteristics of the CT Sim Laser System is usage of movable lasers, a handheld keypad, a power/control box, and a PC controller, which are operated by the CT Sim software to indicate isocenter in the CT suite. These technological characteristics are believed to be substantially equivalent to the predicate device and where differences exist, do not raise new questions of safety and/or effectiveness.

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

The CT Sim Laser System 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**

The CT Sim Laser System is believed to be substantially equivalent to the predicate Philips Laser Alignment Tool (K943381) and Diacor Inc. Centralite (K872489) device due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate CT Sim Laser System is as safe, as effective, and performs as well as the predicate device. Where differences exist, they are not believed to raise new questions of safety and/or effectiveness.