Radialogica LLC
% Ms. Debra Vigil
Director of Quality Assurance and Regulatory Affairs
511 N. Garrison Avenue
SAINT LOUIS MO 63103

April 4, 2018

Re: K180595
Trade/Device Name: SciMoCa
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 1, 2018
Received: March 6, 2018

Dear Ms. Vigil:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180595

Device Name
SCiMoCa

Indications for Use *(Describe)*

SciMoCa is a software product intended to provide quality assurance of a radiotherapy dose calculated by a treatment planning system by allowing a clinician to re-calculate the dose with an independent dose calculation algorithm and compare the two doses.

SciMoCa is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.

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.

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510(k) Summary Statement

510(K) Owner

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Contact person

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Preparation Date

1 March 2018

Trade Name

SciMoCa

Common Name

Secondary Check QA Software

Classification Name

Accelerator, Linear, Medical
21 CFR 892.5050
Product Code: IYE

Class II

Predicate Devices

- K140660 Mobius3D (Mobius Medical Systems, LP)
- K161946 Model 1217028 DoseCHECK (Sun Nuclear Corporation)

Device Description:

SciMoCa is a standalone software product that allows clinicians to perform quality assurance of a radiotherapy treatment dose generated by a treatment planning system via recalculation of the dose with an independent Monte Carlo dose calculation algorithm. SciMoCa is implemented in a service-oriented client-server architecture that allows one or more clients to communicate calculation requests to a central dose calculation server. SciMoCa is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.

Intended Use:

SciMoCa is a software product intended to provide quality assurance of a radiotherapy dose calculated by a treatment planning system by allowing a clinician to re-calculate the dose with an independent dose calculation algorithm and compare the two doses.

SciMoCa is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.

Technological Characteristics:

The primary technological components of SciMoCa and its predicate devices are an independent dose calculation algorithm and functionality that allows comparison between an independently-calculated dose and a dose generated by a treatment planning system, all for quality assurance purposes. The technological characteristics are believed to be substantially equivalent to the predicate devices.

Performance Testing Summary:

Validation testing involved simulated clinical workflows and environment, as well as algorithm testing. These are described in detail in section 18. The product was deemed fit for clinical use.

Non-Clinical Testing Summary:

Verification tests were written and executed, focused on verifying that the product performed to specifications and works as designed. Over 700 tests procedures were executed, including tests to verify requirements for functionality, tests to ensure risk mitigations function as intended, and regression tests to ensure the safety and effectiveness of functionality. SciMoCa passed verification testing and was deemed safe and effective for its intended use.

Conclusion:

SciMoCa is believed to be substantially equivalent to the predicate devices in terms of its indications for use, technical characteristics, and overall performance. The information provided in this submission indicates substantial equivalence to the predicate devices. It is in the opinion of Radialogica, LLC that the medical device, SciMoCa, is as safe, is as effective, and performs as well as the predicate devices.