Carina Medical LLC
℅ Dr. Xue Feng
Chief Executive Officer
1233 Litchfield Lane
LEXINGTON KY 40513

May 13, 2022

Re: K213137
Trade/Device Name: INTDose
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 11, 2022
Received: April 11, 2022

Dear Dr. Xue Feng:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie Sullivan, Ph.D.
Assistant Director
DHT 8C: Division of Radiological Imaging and
Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213137

Device Name
INTDose

Indications for Use *(Describe)*
INTDose is a software product intended to support the radiation therapy treatment planning process by providing independent dose verification through Monte Carlo simulation. INTDose is not a treatment planning system or a radiation delivery device and should only be used by trained radiation oncology personnel as a quality assurance tool.

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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Summary 510(k) K213137

1. Applicant:

Carina Medical LLC
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Lexington, KY, 40513
USA
Contact Name: Xue Feng – Chief Executive Officer
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2. Device:

Trade Name: INTDose
Common Name: Secondary Check QA Software
Model Number: 1.0
Product Code: IYE
Regulation Description: Medical charged-particle radiation therapy system
Regulation Number: 21 CFR 892.5050
Device Class: II

3. Predicate Device:

Trade Name: SciMoCa
Manufacturer: Radialogica, LLC
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Device Class: II
Product Code: IYE
510(k) Number: K180595
510(k) Clearance Date: 04/04/2018

4. Preparation Date

September 16, 2021

5. Device Description

INTDose is a software product used within a radiation therapy clinic for quality assurance and treatment plan verification. It allows clinicians to perform a second check of a radiotherapy dose generated by a treatment planning system by simulating the transport of ionizing radiation in patients using an independent Monte Carlo algorithm. INTDose is implemented such that one or more clients may communicate calculation requests to a central dose calculation server.

While INTDose operates in the field of radiation therapy, it is neither a treatment planning system nor radiation delivery device. INTDose never comes into contact with patients and cannot control treatment delivery devices or any other medical devices. It is an analysis tool to be used only by trained radiation oncology personnel for quality assurance purposes.

6. Intended Use

INTDose is a software product intended to support the radiation therapy treatment planning process by providing independent dose verification through Monte Carlo simulation. INTDose is not a treatment planning system or a radiation delivery device and should only be used by trained radiation oncology personnel as a quality assurance tool.

7. Indications for Use Statement

INTDose is a software product intended to support the radiation therapy treatment planning process by providing independent dose verification through Monte Carlo simulation. INTDose is not a treatment planning system or a radiation delivery device and should only be used by trained radiation oncology personnel as a quality assurance tool.

8. Technological Characteristics

The principal technological characteristic of INTDose and its predicate device is a second check dose calculation algorithm that allows clinicians to compare the dose calculated by a treatment planning system to an independently-calculated second check dose for the purpose of quality

assurance in a radiation medicine clinic. Detailed technological characteristics and indications for use presented in the full set of submitted documentation for this 510(k) application support the claim that INTDose is substantially equivalent to the predicate devices.

9. Performance Data

The safety and performance of INTDose has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Non-clinical verification and validation test results, including simulation performance and software usability, established that the device meets its design requirements and intended use, that it is as safe and as effective as the predicate device, and that no new issues of safety and effectiveness were raised.

The following treatment delivery machines have successfully completed compatibility testing with INTDose

- Accuray TomoTherapy HDA (v2.1.4)
- Varian TrueBeam (v2.0)
- Varian Clinac (21EX-Platinum)
- Varian Clinac (iX)
- Varian Halcyon (v2.0)

Further, during the development, potential hazards were controlled by a risk management plan including risk analysis, risk mitigation, verification and validation.

10. Substantial Equivalence Conclusion

INTDose is believed to be substantially equivalent to the predicate device in terms of its indications for use, technical characteristics, and overall performance. The information provided in this submission indicates substantial equivalence to the predicate device. It is in the opinion of Carina Medical, LLC that the medical device, INTDose, is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness.