October 1, 2025

Nu-Rise, SA
% Keira Jessop
Regulatory Affairs Consultant
AlvaMed
935 Great Plain Avenue
Suite 166
Needham, Massachusetts 02492

Re: K250083
Trade/Device Name: PRO-DOSE System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: NZT, IYE
Dated: January 10, 2025
Received: January 13, 2025

Dear Keira Jessop:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: 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)*
K250083

Device Name
PRO-DOSE System

Indications for Use *(Describe)*
The PRO-DOSE System is intended to provide dosimetry or detect in real-time the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of HDR brachytherapy after-loaders involving Iridium-192 sources.

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

Name and Address of Submitter

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Submission Information

Date Summary Prepared: September 30, 2025

Subject Device:	Trade/Device Name:	PRO-DOSE System
	Manufacturer:	NU-RISE
	Common Name:	
	Regulation Number:	892.5050
	Regulation Name:	Medical charged- particle radiation therapy system
	Regulation Class	II
	Product Code:	NZT, IYE
	Review Panel:	Radiology
Predicate Device:	Clearance:	K092285
	Trade/Device Name:	MOSFET System Portable Dosimeter Dose Verification System, Model TD-RD- 90
	Manufacturer:	Best Medical Canada, Ltd.
	Regulation Number:	892.5050
	Regulation Name:	Medical charged- particle radiation therapy system
	Regulation Class	II
	Product Code:	IYE

Reference Device:	Clearance:	K182395
	Trade/Device Name:	OARtrac System
	Manufacturer:	AngioDynamics (formerly RadiaDyne)
	Regulation Number:	892.5050
	Regulation Name:	Medical charged- particle radiation therapy system
	Regulation Class	II
	Product Code:	NZT

Valid Predicate Discussion

MOSFET System Portable Dosimeter Dose Verification System, Model TD-RD- 90 was selected as the valid predicate device and the OARtrac System was selected as the reference device to support the 510(k) submission because they received FDA clearance using well-established methods. Both the predicate and reference device meet the expected predicate performance due to no reports of unexpected injury, deaths, or malfunctions associated with the device. After conducting a search on the Manufacturer and User Facility Device Experience (MAUDE) Database, Medical Device Reporting (MDR), MedSun Reports Database, Medical Device Safety and CBER Safety & Availability (Biologics) and Recall Database websites, it was found that there are no known unmitigated use-related or design safety issues and the predicate device have not been subject to a design-related recall. Design related recalls were identified in the FDA Database for the reference device. The reason for recall was that the device may result in readings outside of the expected accuracy range. All the recalls were terminated on October 26, 2020.

Table 1: Valid Predicate Device

Valid Predicate Device	**A - Well established methods**	**B - Meets or exceeds expected predicate performance**	**C - Unmitigated use-related or design-related safety issues**	**D – Associated design-related recall**
MOSFET System Portable Dosimeter Dose Verification System, Model TD-RD- 90 (Predicate Device)	Used relevant methods that were published in the public domain.	History of Safe use, established due to duration of device on the market	No known unmitigated use-related or design related safety issues	No design-related recall identified

OARtrac System (Reference Device)	Used relevant methods that were published in the public domain.	History of safe use established due to no reports of unexpected injury, deaths, or malfunctions associated with the device	No known unmitigated use related or design-related safety issues	Design-related recalls identified in the FDA Database

Device Description

The PRO-DOSE System is intended to provide dosimetry or detect in real-time the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of HDR brachytherapy after-loaders involving Iridium-192 sources.

It is designed to measure the total dose and dose rate administered to patients during radiation therapy treatments. It enables real-time, in vivo monitoring throughout the treatment and generates a Dosimetry Report upon completion.

The Reading Device allows simultaneous dosimetry measurements in up to three independent positions by using three probes.

The System can be operated via an Software Graphical User Interface (GUI) that runs on the MiniPC, which functions in kiosk mode to ensure secure and exclusive use. The Software is pivotal in controlling the Reading Device, processing the signal and displaying measurements. As treatment progresses, real-time dose and dose rate measurements are provided. It also allows for the export of a Dosimetry Report as PDF files for documentation and review. The Probes allow instant detection and quantification of radiation dose. These probes are strategically placed at predefined locations by the user to ensure optimal monitoring throughout the treatment. The probes are single-use and pre-calibrated. Due to their small size and water equivalence, these probes can be inserted into the patient body using the same techniques through needles used in the HDR brachytherapy treatments.

The real-time radiation dose data is intended for use by qualified and trained personnel who recognize radiation hazards associated with the use of radiation therapy and radiology equipment. The system does not interact with the radiation source and is solely designed to monitor and report the accuracy of the treatment delivery. It does not deliver, plan, simulate, or control the radiation delivery. The trained and qualified user is responsible for the interpretation of the information.

The current version of PRO-DOSE System is specifically suitable for monitoring High Dose Rate (HDR) Brachytherapy treatments involving Iridium-192 sources.

Indications for Use

The PRO-DOSE System is intended to provide dosimetry or detect in real-time the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of HDR brachytherapy after-loaders involving Iridium-192 sources.

Summary of Technological Characteristics

.	Subject Device	Predicate Device	Reference Device
Trade Name	PRO-DOSE System	Portable Dosimeter Dose Verification System, Model TD-RD-90 (MOSFET System)	OARtrac System
510(k) Number	K250083	K092285	K182395
Indications for Use	The PRO-DOSE System is intended to provide dosimetry or detect in real-time the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of HDR brachytherapy after-loaders involving Iridium-192 sources.	To provide dosimetry or to detect the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of radiation producing devices.	The OARtrac System with patient specific, reusable up to five times, precalibrated PSD sensors are intended for use during cancer treatments to measure photon and electron radiation therapy as an adjunct to treatment planning permitting measurement and validation of radiation dose received by the patient to the targeted area of their body. The system is indicated for use with electron energy when adhered to the skin with or without a bolus, and for photon energy when adhered to the skin with a minimum 3mm bolus or inserted into the rectum for measurements at the rectal wall during cancer treatment via a specifically designed OARtrac endorectal balloon device.
Regulation Number	892.5050	892.5050	892.5050
Regulation Name	Medical charged- particle radiation therapy system	Medical charged- particle radiation therapy system	Medical charged- particle radiation therapy system
Device Class	II	II	II
Product Code	NZT, IYE	IYE	NZT
Technology	Fiber Optic	Semiconductor	Fiber Optic
Dose Monitoring	Continuous Real Time	Total dose after irradiation or updates every 20	-

.	Subject Device	Predicate Device	Reference Device
		seconds	
How Provided and Use	Clean, Single Use	Clean, Reusable	Clean, Reusable
Location of Use	Within the body in conjunction with catheters	Adhered to skin, or within the body in conjunction with catheters	Adhered to skin, or within rectal balloon accessory device
Accessories	Probes are connected to Reading Device, which is connected to software running on a miniPC	Probes are connected to Reading Unit which displays the measurements, data can be transferred to a computer via USB	Rectal balloon and Connectors
Use Setting(s) & Environment	For use during brachytherapy at Hospital or Radiation Therapy Clinic	For use during radiation beam therapy or brachytherapy at Hospital or Radiation Therapy Clinic	For use during radiation beam therapy or brachytherapy at Hospital or Radiation Therapy Clinic

The difference in the indications between the subject and predicate device do not affect the safety and effectiveness. Differences in the two indications are related to the time period in which the dose amount is provided and the radiation source of which the output is being verified. The subject device is able to provide the dose and dose rate during the procedure in real time while the predicate provides information only about total dose after irradiation or updates every 20 seconds. The subject device is also specific to verifying the output of HDR brachytherapy after-loaders involving Iridium-192 sources, which is a subset of the predicate's indication of "radiation producing sources. These differences are due to the device technology or specific testing conducted and test set-up, but the intended use of the device remains the same.

With regards to the technology between the subject and predicate device, there are minor differences, but they do not affect the safety and effectiveness of the device. The subject device is inserted into standard brachytherapy needles or catheters, while the predicate device can either be inserted in the same manner or adhered to the skin. The subject device probes are single use, while the predicate probes are reusable until their useful life. The subject device uses fiber optic technology, while the predicate uses semiconductor technology. It should be noted that the reference device uses fiber optic technology. In the predicate device, the dosimetry records can be transferred to a computer through a USB connection, while the subject device is connected to software running on a computer through an ethernet cable. The fiber optic technology and connection to software allow for real time dosimetry readings, which is not available with the predicate device. The intended use of both devices is dosimetry readings, and any technological differences do not impact this. None of the technology differences represent new technology.

Performance Testing Summary

Summary of Non-Clinical Functional and Performance Testing

The following tests were performed to evaluate the performance and safety of the device.

- EMC/Electrical Safety Software Validation per IEC60601-1, IEC 60601-1-2, and FDA Guidance document, Electromagnetic Compatibility (EMC) of Medical Devices
- Conditioning and Transit Validation per ASTM ASTM D4332-22 and ASTM D4169-22
- Shelf-life Testing for probes per ASTM F1980-21
- Cycle Testing to determine use life of the Reading device
- Operating Ranges Testing to confirm device operates within labeled humidity and temperature conditions
- Mechanical Integrity for:
    - Handling and bending of probe
    - Probe integrity with needle fixer
- Physical and Dosimetrical Bench Characterization
    - Accuracy
    - Linearity
    - Repeatability
    - Stability
    - Calibration
    - Angular/Spatial Response
- Phantom Testing
    - Ensure device meets performance specifications in representative simulated use phantoms
- Cleaning Validation to demonstrate effectiveness of cleaning and that device functionality is maintained
- Human Factors Validation per IEC 62366 and FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices
- Software Validation per IEC 62304 and FDA guidance document, Content of Premarket Submissions for Device Software Functions
- Cybersecurity Assessment per FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Summary of Animal and Clinical Data

No animal or clinical studies were conducted to demonstrate safety of the device.

Conclusion

Based on the information presented in this Premarket Notification, NU-RISE concludes that PRO-DOSE is substantially equivalent to the predicate based on the same intended use. Any differences in technological characteristics between the subject and predicate device have demonstrated continued performance and do not raise issues of safety and effectiveness.