

**K250083 PRO-DOSE System**Oct 1, 2025  
261 days to decisionK250083 · Product code: **NZT** · Radiology  
Source: <https://www.510kdatabase.net/k250083/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dosimeter, Ionizing Radiation, Implanted (NZT)
Date received	Jan 13, 2025
Decision date	Oct 1, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nu-Rise, SA</b>
Location	Ilhavo, PT
Contact	Joana Melo
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Alvamed</b>
Contact	Keira Jessop

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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