

**K250963 PlanOne 1**Nov 20, 2025  
234 days to decisionK250963 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k250963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Mar 31, 2025
Decision date	Nov 20, 2025
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cosylab Jsc, Control System Laboratory</b>
Location	Ljubljana, SI
Contact	Matija Rupnik
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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