

K253004 LUNA 3DJun 4, 2026
258 days to decisionK253004 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k253004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 19, 2025
Decision date	Jun 4, 2026
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lap GmbH Laser Applikationen
Location	Lueneburg, DE
Contact	Sebastian Boldhaus
510(k) history	4 submissions · 4 cleared · 2018-2026

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