

K254010 ExacTrac Dynamic (2.0.2)Jan 14, 2026
30 days to decisionK254010 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k254010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 15, 2025
Decision date	Jan 14, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ExacTrac Dynamic Surface

APPLICANT

Company	Brainlab SE
Location	Munich, DE
Contact	Sadwini Suresh
510(k) history	1 submissions · 1 cleared · 2026-2026

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