

K252188 EMLA (Elekta Evo)Jan 15, 2026
185 days to decisionK252188 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k252188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 14, 2025
Decision date	Jan 15, 2026
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EMLA (VersaHD); EMLA (Elekta Harmony Pro); EMLA (Elekta Infintiy); EMLA (Elekta Harmony); EMLA (Elekta Synergy)

APPLICANT

Company	Elekta Solutions AB
Location	Stockholm, SE
Contact	Lorenzo Muratori
510(k) history	14 submissions · 14 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252188/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026