

K210500 Elekta Synergy, Elekta Harmony, Elekta Infinity, Versa HDJun 11, 2021
109 days to decisionK210500 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k210500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Feb 22, 2021
Decision date	Jun 11, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elekta Limited
Location	West Sussex, GB
Contact	Lorenzo Muratori
510(k) history	8 submissions · 8 cleared · 2011-2021

REGULATORY CONSULTANT

Consulting firm	Elekta, Inc.
Contact	Lorenzo Muratori

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210500/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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