

K192482 Elekta UnityDec 5, 2019
86 days to decisionK192482 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k192482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 10, 2019
Decision date	Dec 5, 2019
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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