FDA 510(k) Premarket Notification

K082122 MLCI2

CLEARED

Aug 29, 2008
32 days to decision

K082122 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k082122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 28, 2008
Decision date	Aug 29, 2008
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Elekta , Ltd.**
Location	Norcross, GA, US
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510(k) history	10 submissions · 10 cleared · 2005-2014