

K161946 DoseCHECKSep 16, 2016
63 days to decisionK161946 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k161946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 15, 2016
Decision date	Sep 16, 2016
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sun Nuclear Corporation
Location	Melbourne, FL, US
Contact	Rene' Hardee
510(k) history	11 submissions · 11 cleared · 2013-2017

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