

K170307 SunCHECKOct 25, 2017
266 days to decisionK170307 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k170307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Feb 1, 2017
Decision date	Oct 25, 2017
Days to decision	266 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170307/> 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 16, 2026