

**K121845 SDX SYSTEM**Oct 19, 2012  
116 days to decisionK121845 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k121845/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jun 25, 2012
Decision date	Oct 19, 2012
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dyn&amp;apos;R Sas</b>
Location	Aix En Provence, FR
Contact	TIM LAWTON
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121845/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026