

**K182374 LIAC S**May 22, 2019  
264 days to decisionK182374 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k182374/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 31, 2018
Decision date	May 22, 2019
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sit Sordina Iort Technologies Spa</b>
Location	Vicenza, IT
Contact	Alessia Giaffreda
510(k) history	2 submissions · 2 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Isemed S.R.L.</b>
Contact	Maurizio Pantaleoni

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182374/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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