

**K172961 LIAC HWL**Jun 11, 2018  
258 days to decisionK172961 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k172961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 26, 2017
Decision date	Jun 11, 2018
Days to decision	258 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](https://accessdata.fda.gov)

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