FDA 510(k) Premarket Notification

K172961 LIAC HWL

CLEARED

Jun 11, 2018
258 days to decision

K172961 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k172961/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Isemed S.R.L.**
Contact	Maurizio Pantaleoni

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