

K151207 Proton Immobilization SolutionJul 28, 2015
83 days to decisionK151207 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k151207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 6, 2015
Decision date	Jul 28, 2015
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orfit Industries NV
Location	Wijnegem, BE
Contact	EDDY MARIVOET
510(k) history	9 submissions · 9 cleared · 2013-2020

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