

**K151946 Thermofit**Nov 9, 2015  
118 days to decisionK151946 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k151946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 14, 2015
Decision date	Nov 9, 2015
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Orfit Industries</b>
Location	Wijnegem, Belgium, BE
Contact	EDDY MAROVOET
510(k) history	2 submissions · 2 cleared · 1999-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151946/> 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 16, 2026