

K162355 Raycast MammoRx Carbon Fibre Breast BoardNov 22, 2016
91 days to decisionK162355 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k162355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 23, 2016
Decision date	Nov 22, 2016
Days to decision	91 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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