

**K131795 NANOR AND EFFICAST/NANOR HYBRID
THERMOPLASTIC MATERIALS**Sep 26, 2013
100 days to decisionK131795 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k131795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jun 18, 2013
Decision date	Sep 26, 2013
Days to decision	100 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131795/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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