

K191158 The AIO SolutionAug 6, 2019
97 days to decisionK191158 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k191158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 1, 2019
Decision date	Aug 6, 2019
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Arazy Group Consultants, Inc.
Contact	Ray Kelly

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

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