

**K202068 The AIO Solution 3.0**Aug 14, 2020  
18 days to decisionK202068 · Product code: IYE · Radiology  
Source: <https://www.510kdatabase.net/k202068/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 27, 2020
Decision date	Aug 14, 2020
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Arazy Group Consultants, Inc.</b>
Contact	Ray Kelly

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202068/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 15, 2026