

K200282 Orfit Aerial CouchtopApr 8, 2020
64 days to decisionK200282 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k200282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Feb 4, 2020
Decision date	Apr 8, 2020
Days to decision	64 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](https://accessdata.fda.gov)

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