

**K212237 3D-Cut**Nov 29, 2021  
133 days to decisionK212237 · Product code: **PBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k212237/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Jul 19, 2021
Decision date	Nov 29, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3D-Side S.A.</b>
Location	Mont-Saint-Guibert, BE
Contact	Laurent Paul
510(k) history	3 submissions · 3 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Orthogrow NV</b>
Contact	Niels Festjens

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212237/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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