

**K183613 exGraft, exGraft Carbon**Apr 22, 2019  
117 days to decisionK183613 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k183613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Dec 26, 2018
Decision date	Apr 22, 2019
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Peca Labs</b>
Location	Pittsburgh, PA, US
Contact	Doug Bernstein
510(k) history	4 submissions · 4 cleared · 2018-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183613/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026