

K180957 exGraft, exGraft Carbon ePTFE Vascular GraftsAug 21, 2018
131 days to decisionK180957 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k180957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Apr 12, 2018
Decision date	Aug 21, 2018
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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