

K221628 exGraft, exGraft CarbonAug 4, 2022
59 days to decisionK221628 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k221628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jun 6, 2022
Decision date	Aug 4, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	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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