

K203437 Serranator PTA Serration Balloon CatheterDec 22, 2020
29 days to decisionK203437 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k203437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Nov 23, 2020
Decision date	Dec 22, 2020
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cagent Vascular, LLC
Location	Wayne, PA, US
Contact	Carol Burns
510(k) history	5 submissions · 5 cleared · 2017-2022

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