

K193181 Serranator PTA Serration Balloon CatheterApr 15, 2020
149 days to decisionK193181 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k193181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Nov 18, 2019
Decision date	Apr 15, 2020
Days to decision	149 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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