

K213728 Serranator PTA Serration Balloon CatheterDec 15, 2021
19 days to decisionK213728 · Product code: **PNO** · CardiovascularSource: <https://www.510kdatabase.net/k213728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Nov 26, 2021
Decision date	Dec 15, 2021
Days to decision	19 days
Third-party review	No
Combination product	No
PCCP authorized	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213728/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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