

K220704 Serranator PTA Serration Balloon CatheterMay 4, 2022
55 days to decisionK220704 · Product code: **PNO** · CardiovascularSource: <https://www.510kdatabase.net/k220704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Mar 10, 2022
Decision date	May 4, 2022
Days to decision	55 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

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