

**K163380 Serranator Alto PTA Serration Balloon Catheter**Feb 13, 2017  
74 days to decisionK163380 · Product code: **PNO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163380/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Dec 1, 2016
Decision date	Feb 13, 2017
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163380/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026