

**K222185 Stratus Infusion Catheter**Apr 13, 2023  
265 days to decisionK222185 · Product code: **NPG** · CardiovascularSource: <https://www.510kdatabase.net/k222185/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Infusion, Syringe (NPG)
Date received	Jul 22, 2022
Decision date	Apr 13, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Intervene, Inc.</b>
Location	South San Francisco, CA, US
Contact	Jeff Elkins
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mark Smutka</b>
Contact	Mark Smutka

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222185/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026