FDA 510(k) Premarket Notification

K222185 Stratus Infusion Catheter

CLEARED

Apr 13, 2023
265 days to decision

K222185 · Product code: **NPG** · Cardiovascular
Source: 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	**Intervene, Inc.**
Location	South San Francisco, CA, US
Contact	Jeff Elkins
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Mark Smutka**
Contact	Mark Smutka

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov