

K232037 Reprocessed VersaCross Steerable SheathApr 4, 2024
269 days to decisionK232037 · Product code: **PNE** · Cardiovascular
Source: <https://www.510kdatabase.net/k232037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Jul 10, 2023
Decision date	Apr 4, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Reprocessed SureFlex Steerable Guiding Sheath

APPLICANT

Company	Innovative Health, LLC
Location	Scottsdale, AZ, US
Contact	Rick Ferreira
510(k) history	48 submissions · 48 cleared · 2016-2024

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