

**K250314 Medline ReNewal Reprocessed Abbott Agilis Nxt
Steerable Introducer**Dec 19, 2025
318 days to decisionK250314 · Product code: **PNE** · Cardiovascular
Source: <https://www.510kdatabase.net/k250314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Feb 4, 2025
Decision date	Dec 19, 2025
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Instrument Service and Savings, Inc.
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	23 submissions · 23 cleared · 2016-2025

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