

K250305 Reprocessed Agilis NxT Steerable IntroducerJan 7, 2026
338 days to decisionK250305 · Product code: **PNE** · CardiovascularSource: <https://www.510kdatabase.net/k250305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Feb 3, 2025
Decision date	Jan 7, 2026
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Health
Location	Scottsdale, AZ, US
Contact	Rick Ferreira
510(k) history	2 submissions · 2 cleared · 2024-2026

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