

K230376 Reprocessed Agilis NxT Steerable IntroducerAug 7, 2023
175 days to decisionK230376 · Product code: **PNE** · CardiovascularSource: <https://www.510kdatabase.net/k230376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Feb 13, 2023
Decision date	Aug 7, 2023
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230376/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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