FDA 510(k) Premarket Notification

CLEARED

K170311 Reprocessed Agilis NxT Steerable Introducer

Jun 2, 2017
121 days to decision

K170311 · Product code: **PNE** · Cardiovascular
Source: https://www.510kdatabase.net/k170311/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Feb 1, 2017
Decision date	Jun 2, 2017
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innovative Health, LLC**
Location	Scottsdale, AZ, US
Contact	Amy Stoklas-Oakes
510(k) history	48 submissions · 48 cleared · 2016-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k170311/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026