FDA 510(k) Premarket Notification

K230376 Reprocessed Agilis NxT Steerable Introducer

CLEARED

Aug 7, 2023
175 days to decision

K230376 · Product code: **PNE** · Cardiovascular
Source: 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