FDA 510(k) Premarket Notification

K171503 Reprocessed CristaCath Diagnostic Electrophysiology Catheter

CLEARED

Oct 5, 2017
135 days to decision

K171503 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k171503/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	May 23, 2017
Decision date	Oct 5, 2017
Days to decision	135 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/k171503/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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