FDA 510(k) Premarket Notification

CLEARED

K160303 Reprocessed Polaris X Steerable Diagnostic EP Catheter

May 10, 2016
96 days to decision

K160303 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k160303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Feb 4, 2016
Decision date	May 10, 2016
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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