K191170 Reprocessed Reflexion Spiral Bi-Directional Variable Radius Electrophysiology Catheter

CLEARED

Oct 30, 2019
182 days to decision

K191170 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k191170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	May 1, 2019
Decision date	Oct 30, 2019
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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