

K190785 Reprocessed PentaRay Nav eco High-Density Mapping Catheter

Jun 25, 2019
90 days to decisionK190785 · Product code: **NLG** · Cardiovascular
Source: <https://www.510kdatabase.net/k190785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density, Reprocessed (NLG)
Date received	Mar 27, 2019
Decision date	Jun 25, 2019
Days to decision	90 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

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