

K163560 Reprocessed AcuNav Diagnostic Ultrasound CatheterJul 12, 2017
205 days to decisionK163560 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k163560/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Dec 19, 2016
Decision date	Jul 12, 2017
Days to decision	205 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

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