

K181126 Reprocessed Visions PV .035 Digital IVUS CatheterJan 18, 2019
263 days to decisionK181126 · Product code: **OWQ** · CardiovascularSource: <https://www.510kdatabase.net/k181126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Apr 30, 2018
Decision date	Jan 18, 2019
Days to decision	263 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181126/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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