

K173262 Reprocessed ViewFlex Xtra Ice Diagnostic Ultrasound Catheter

Mar 6, 2018
146 days to decision

K173262 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k173262/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Oct 11, 2017
Decision date	Mar 6, 2018
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Health, LLC
Location	Scottsdale, AZ, US
Contact	Amy Stoklas-Oakes
510(k) history	48 submissions · 48 cleared · 2016-2024

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Device record: <https://www.510kdatabase.net/k173262/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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