

K202042 Reprocessed ViewFlex Xtra Ice Diagnostic Ultrasound Catheter

Nov 20, 2020
120 days to decision

K202042 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k202042/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Jul 23, 2020
Decision date	Nov 20, 2020
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202042/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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