

K182238 Reprocessed ViewFlex Xtra ICE CatheterMay 8, 2019
261 days to decisionK182238 · Product code: **OWQ** · CardiovascularSource: <https://www.510kdatabase.net/k182238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Aug 20, 2018
Decision date	May 8, 2019
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Sustainability Solutions
Location	Tempe, AZ, US
Contact	Ramona Kulik
510(k) history	31 submissions · 31 cleared · 2011-2025

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