

K232130 Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter

Dec 15, 2023
151 days to decision

K232130 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k232130/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Jul 17, 2023
Decision date	Dec 15, 2023
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Instrument Services and Savings, Inc.
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	4 submissions · 4 cleared · 2015-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k232130/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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