

K190478 Reprocessed ViewFlex™ Xtra ICE CatheterNov 14, 2019
260 days to decisionK190478 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k190478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Feb 27, 2019
Decision date	Nov 14, 2019
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterilmed, Inc.
Location	Plymouth, MN, US
Contact	Jan Flegeau
510(k) history	64 submissions · 64 cleared · 2001-2024

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