FDA 510(k) Premarket Notification

# K231621 Reprocessed ViewFlex Xtra ICE Catheter (D087031)

**CLEARED**

Jul 25, 2023
53 days to decision

K231621 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k231621/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Reprocessed Intravascular Ultrasound Catheter (OWQ) |
| Date received | Jun 2, 2023 |
| Decision date | Jul 25, 2023 |
| Days to decision | 53 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Stryker Sustainability Solutions** |
| Location | Tempe, AZ, US |
| Contact | Mia Brown |
| 510(k) history | 31 submissions · 31 cleared · 2011-2025 |