FDA 510(k) Premarket Notification

**CLEARED**

# K222217 ViewFlex Xtra Reprocessed ICE Catheter

Dec 19, 2022
147 days to decision

K222217 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k222217/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reprocessed Intravascular Ultrasound Catheter (OWQ) |
| Date received | Jul 25, 2022 |
| Decision date | Dec 19, 2022 |
| Days to decision | 147 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Abbott Medical** |
| Location | S,Mta Clara, CA, US |
| Contact | Quynh Phuong Le |
| Website | https://www.abbott.com |
| 510(k) history | 57 submissions · 57 cleared · 2019-2026 |

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...