FDA 510(k) Premarket Notification

K251211 ViewFlex™ Xtra ICE Catheter

CLEARED

May 23, 2025
35 days to decision

K251211 · Product code: **OBJ** · Cardiovascular
Source: https://www.510kdatabase.net/k251211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Apr 18, 2025
Decision date	May 23, 2025
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ViewFlex™ Eco Reprocessed ICE Catheter; Advisor™ HD Grid Mapping Catheter, Sensor Enabled™; Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™; Agilis™ NxT Steerable Introducer; Agilis™ NxT Steerable Introducer Dual-Reach™

APPLICANT

Company	**Abbott Medical**
Location	S,Mta Clara, CA, US
Contact	Adam Bakken
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...