

K241576 Makoto Intravascular Imaging System™ (VC-MC10 / TVC-MC10i)Feb 26, 2025
268 days to decisionK241576 · Product code: **OGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k241576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Jun 3, 2024
Decision date	Feb 26, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Dualpro™ IVUS+NIRS Imaging Catheter (TVC-C195-42); Peripheral 014 Imaging Catheter (TVC-E195-42)

APPLICANT

Company	Infraredx, Inc.
Location	Burlington, MA, US
Contact	Stephen Sum
510(k) history	11 submissions · 11 cleared · 2006-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241576/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026