

**K141682 TVC IMAGING SYSTEM, TVC INSIGHT CATHETER**Nov 24, 2014  
154 days to decisionK141682 · Product code: **OGZ** · CardiovascularSource: <https://www.510kdatabase.net/k141682/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Jun 23, 2014
Decision date	Nov 24, 2014
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Infraredx, Inc.</b>
Location	Burlington, MA, US
Contact	STEVEN J CHARTIER
510(k) history	11 submissions · 11 cleared · 2006-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141682/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026