

K133897 TVC IMAGING SYSTEM, TVC INSIGHT CATHETERApr 23, 2014
124 days to decisionK133897 · Product code: **OGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k133897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Dec 20, 2013
Decision date	Apr 23, 2014
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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