

K130719 TVC IMAGING SYSTEM, TVC INSIGHT CATHETEROct 17, 2013
213 days to decisionK130719 · Product code: **OGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k130719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Mar 18, 2013
Decision date	Oct 17, 2013
Days to decision	213 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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