

K163345 TVC Imaging System, TVC CatheterJun 21, 2017
204 days to decisionK163345 · Product code: **OGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k163345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Nov 29, 2016
Decision date	Jun 21, 2017
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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