

K123108 TVC IMAGING SYSTEM MODEL NIRS-MC7-70Mar 15, 2013
163 days to decisionK123108 · Product code: **OGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k123108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Oct 3, 2012
Decision date	Mar 15, 2013
Days to decision	163 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123108/> 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 26, 2026