

K093993 LIPISCAN IVUS IMAGING SYSTEM MODEL NIRS-MC7-70Jun 30, 2010
188 days to decisionK093993 · Product code: **OGZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k093993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Dec 24, 2009
Decision date	Jun 30, 2010
Days to decision	188 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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