

**K072932 INFRAREDIX NIR IMAGING SYSTEM, GEN. 1.0, MODEL MC-5**Apr 25, 2008  
192 days to decisionK072932 · Product code: **OGZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k072932/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Oct 16, 2007
Decision date	Apr 25, 2008
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072932/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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