

**K183599 Makoto Intravascular Imaging System, Dualpro IVUS + NIRS Imaging Catheter**Apr 12, 2019  
107 days to decisionK183599 · Product code: **OGZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k183599/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Plaque Morphology Evaluation (OGZ)
Date received	Dec 26, 2018
Decision date	Apr 12, 2019
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infraredx, Inc.</b>
Location	Burlington, MA, US
Contact	Stephen Sum
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/k183599/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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