

**K213303 Makoto Intravascular Imaging System, TVC-MC10/TVC-MC10i, Dualpro IVUS + NIRS Imaging Catheter ,TVC-C195-42, Peripheral 014 Imaging Catheter, TVC-E195-42**Dec 7, 2021  
64 days to decisionK213303 · Product code: **IYO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213303/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 4, 2021
Decision date	Dec 7, 2021
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	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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