

**K220490 ImaCor Zura Handheld ZHH-010**Apr 8, 2022  
45 days to decisionK220490 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k220490/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 22, 2022
Decision date	Apr 8, 2022
Days to decision	45 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imacor, Inc.</b>
Location	Uniondale, NY, US
Contact	Richard Lanzillo
510(k) history	3 submissions · 3 cleared · 2010-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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