FDA 510(k) Premarket Notification

K220490 ImaCor Zura Handheld ZHH-010

CLEARED

Apr 8, 2022
45 days to decision

K220490 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k220490/

SUBMISSION DETAILS

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

Company	**Imacor, Inc.**
Location	Uniondale, NY, US
Contact	Richard Lanzillotto
510(k) history	3 submissions · 3 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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