

K100989 ZURA TEE SYSTEM WITH CLARITEE PROBE

Jun 25, 2010
77 days to decision

K100989 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k100989/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 9, 2010
Decision date	Jun 25, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100989/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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