

K101091 Z.ONE ULTRA ULTRASOUND SYSTEMJun 25, 2010
67 days to decisionK101091 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k101091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 19, 2010
Decision date	Jun 25, 2010
Days to decision	67 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Zonare Medical Systems, Inc.
Location	Mountain View, CA, US
Contact	LINDA MOORE
510(k) history	6 submissions · 6 cleared · 2008-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026