

K150249 ZONARE ZS3 and Z.Onepro Diagnostic Ultrasound SystemMar 4, 2015
29 days to decisionK150249 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k150249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 3, 2015
Decision date	Mar 4, 2015
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150249/>; 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