

**K112539 CHISON DIGITAL ULTRASOUND SYSTEM, CONVEX PROBE, LINEAR PROBE, TRANSVAGINAL MICRO-CONVEX PROBE, TRANSRECTAL LINEAR PROBE**Jan 30, 2012  
151 days to decisionK112539 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k112539/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 1, 2011
Decision date	Jan 30, 2012
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Leiker Regulatory &amp; Quality Consulting</b>
Location	Dublin, CA, US
Contact	BOB LEIKER
510(k) history	1 submissions · 1 cleared · 2012-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112539/> 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 17, 2026