

**K140854 INTRA-OPERATIVE ULTRASOUND TRANSDUCER**Jun 11, 2014  
69 days to decisionK140854 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k140854/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 3, 2014
Decision date	Jun 11, 2014
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hitachi Aloka Medical, Ltd.</b>
Location	Wallingford, CT, US
Contact	ANGELA VANARSDALE
510(k) history	6 submissions · 6 cleared · 2012-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140854/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026