

**K042369 SONOSCAPE ULTRASOUND SYSTEM  
SSI-1000/SSI-5000**Oct 20, 2004  
50 days to decisionK042369 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k042369/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 31, 2004
Decision date	Oct 20, 2004
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sonoscape Company Limited</b>
Location	Dublin, CA, US
Contact	BOB LEIKER
510(k) history	22 submissions · 22 cleared · 2004-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042369/>; 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