

**K092997 ULTRASONIC TABLETOP DOPPLER, MODELS SD5  
AND SD6**Nov 10, 2009  
43 days to decisionK092997 · Product code: **KNG** · Radiology  
Source: <https://www.510kdatabase.net/k092997/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Sep 28, 2009
Decision date	Nov 10, 2009
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	WILLIAM STERN
Website	<a href="https://www.edan.com.cn">https://www.edan.com.cn</a>
510(k) history	92 submissions · 92 cleared · 2004-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092997/> 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 17, 2026