

**K080087 SONOTRAX ULTRASONIC FETAL AND VASCULAR
POCKET DOPPLER, MODELS LITE, BASIC, PRO, II, II PRO AND
VASCULAR**Mar 11, 2008
60 days to decisionK080087 · Product code: **KNG** · Radiology
Source: <https://www.510kdatabase.net/k080087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Jan 11, 2008
Decision date	Mar 11, 2008
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080087/> 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 18, 2026