

K252669 Fetal Doppler U8-25, U9-25Jan 8, 2026
136 days to decisionK252669 · Product code: **KNG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k252669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Aug 25, 2025
Decision date	Jan 8, 2026
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhongshan Xiaolan Town Senlan Electronic Factory
Location	Zhongshan, CN
Contact	Runtong Zhong
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Shenzhen Aisnwei Medical Technology Service Co., Ltd.
Contact	Ailing Fu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252669/> 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 13, 2026