

K182710 Fetal Doppler, Model FD88Mar 1, 2019
155 days to decisionK182710 · Product code: **KNG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k182710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Sep 27, 2018
Decision date	Mar 1, 2019
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Luckcome Technology Inc., Ltd.
Location	Shenzhen, CN
Contact	Can He
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182710/> 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 June 28, 2026