FDA 510(k) Premarket Notification

K182526 Fetal Doppler (Models: FD-231B, FD-231D, FD-640B, FD-640D, FD-200B, FD-200D, FD-591B, and FD-591D)

CLEARED

May 29, 2019
260 days to decision

K182526 · Product code: **KNG** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k182526/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Sep 11, 2018
Decision date	May 29, 2019
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vcomin Technology Limited**
Location	Shenzhen, CN
Contact	Han JieLin
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Lucy Yan

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