FDA 510(k) Premarket Notification

K233823 Ultrasonic Fetal Doppler

CLEARED

Jun 28, 2024
210 days to decision

K233823 · Product code: **KNG** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k233823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Dec 1, 2023
Decision date	Jun 28, 2024
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shenzhen Jamr Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Haiyu Zhang
510(k) history	6 submissions · 6 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.**
Contact	Reanny Wang

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