FDA 510(k) Premarket Notification

K182190 Fetal Doppler

CLEARED

Dec 19, 2018
128 days to decision

K182190 · Product code: **KNG** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k182190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Aug 13, 2018
Decision date	Dec 19, 2018
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen AOJ Medical Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Qihuan Zhao
510(k) history	17 submissions · 17 cleared · 2018-2026