FDA 510(k) Premarket Notification

K211940 Fetal Doppler

CLEARED

Jan 7, 2022
198 days to decision

K211940 · Product code: **KNG** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k211940/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Jun 23, 2021
Decision date	Jan 7, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Taikang Medical Equipment Co., Ltd.**
Location	Shenzhen, CN
Contact	Shigui Du
510(k) history	1 submissions · 1 cleared · 2022-2022