

K100626 DOPPLER FETAL HEART RATE DETECTOR, MODEL FM-200May 21, 2010
77 days to decisionK100626 · Product code: **KNG** · Radiology
Source: <https://www.510kdatabase.net/k100626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Mar 5, 2010
Decision date	May 21, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Biocare Electronics Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	5 submissions · 5 cleared · 2010-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100626/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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