

K232893 Pocket Fetal Doppler (CONTEC 10D), Pocket Fetal Doppler (CONTEC 10E), Pocket Fetal Doppler (CONTEC 10F)Jun 14, 2024
270 days to decisionK232893 · Product code: **KNG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k232893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Sep 18, 2023
Decision date	Jun 14, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Contec Medical Systems Co.,Ltd
Location	Shanghai, CN
Contact	Jie Xiao
Website	http://www.contecmed.com/
510(k) history	12 submissions · 12 cleared · 2011-2024

Contec Medical Systems Co., Ltd is a high-tech medical device manufacturer founded in 1996. The company is headquartered in Qinhuangdao, Hebei Province, China, with a manufacturing facility in Shanghai. Contec develops and distributes diagnostic and monitoring devices across multiple therapeutic areas. The company has received FDA 510(k) clearances from total submissions between 2011 and 2024. Contec specializes in cardiovascular devices, including electronic sphygmomanometers, ambulatory blood pressure monitors, and electrocardiographs. The company also manufactures ultr...

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232893/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026