

**K220245 Pocket Fetal Doppler (Models CONTEC10C and CONTEC10CL)**Sep 28, 2022  
243 days to decisionK220245 · Product code: **KNG** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k220245/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Jan 28, 2022
Decision date	Sep 28, 2022
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contec Medical Systems Co.,Ltd</b>
Location	Shanghai, CN
Contact	Jie Xiao
Website	<a href="http://www.contecmed.com/">http://www.contecmed.com/</a>
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**

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Consulting firm	<b>Beijing Believe-Med Technology Service Co., Ltd.</b>
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)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k220245/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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