

**K170954 Portable ECG Monitor**May 30, 2017  
60 days to decisionK170954 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 31, 2017
Decision date	May 30, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contec Medical Systems Co.,Ltd</b>
Location	Shanghai, CN
Contact	Xueyong Li
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...

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