

K152863 Portable ECG MonitorJun 22, 2016
266 days to decisionK152863 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k152863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Sep 30, 2015
Decision date	Jun 22, 2016
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Contec Medical Systems Co.,Ltd
Location	Shanghai, CN
Contact	XUEYONG LI
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...
