

**K201359 ECG Cables and Leadwires**Oct 1, 2020  
133 days to decisionK201359 · Product code: **DSA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	May 21, 2020
Decision date	Oct 1, 2020
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xinkang Medical Instrument Co. , Ltd.</b>
Location	Shenzhen, CN
Contact	Xu Changsheng
510(k) history	2 submissions · 2 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Field Fu

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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