

**K230834 CARDIPIA ECG / Model: CARDIPIA400H, CARDIPIA800H**

Nov 21, 2023  
239 days to decision

K230834 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230834/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 27, 2023
Decision date	Nov 21, 2023
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trismed Co., Ltd.</b>
Location	Daejeon, KR
Contact	Sul Ki Lee
510(k) history	1 submissions · 1 cleared · 2023-2023

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

Device record: <https://www.510kdatabase.net/k230834/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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