

**K183369 COR12 ECG**Dec 28, 2018  
24 days to decisionK183369 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k183369/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 4, 2018
Decision date	Dec 28, 2018
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Corscience GmbH &amp; Co.</b>
Location	Erlangen, DE
Contact	Karlheinz Trost
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Mark Job

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183369/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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