

**K183437 AirRay Subdural Cortical Electrodes**Mar 12, 2019  
90 days to decisionK183437 · Product code: **GYC** · Neurology  
Source: <https://www.510kdatabase.net/k183437/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	Dec 12, 2018
Decision date	Mar 12, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cortec GmbH</b>
Location	Freiburg, DE
Contact	Mara Assis
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183437/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026