

**K212883 ers2 - ergoline Rehabilitation System**Jul 15, 2022  
308 days to decisionK212883 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Sep 10, 2021
Decision date	Jul 15, 2022
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ergoline GmbH</b>
Location	Bitz, B-W, DE
Contact	Alexandra Lertz
510(k) history	3 submissions · 3 cleared · 2006-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212883/> 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 May 27, 2026