

**K182040 Coala Heart Monitor**Feb 8, 2019  
193 days to decisionK182040 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182040/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jul 30, 2018
Decision date	Feb 8, 2019
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coala Life AB</b>
Location	Stockholm, SE
Contact	Philip Siberg
510(k) history	2 submissions · 2 cleared · 2019-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182040/> 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