

**K192004 Eko Analysis Software**Jan 15, 2020  
173 days to decisionK192004 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 26, 2019
Decision date	Jan 15, 2020
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eko Devices, Inc.</b>
Location	Berkeley, CA, US
Contact	Connor Landgraf
510(k) history	6 submissions · 6 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192004/> 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