

**K230881 Change Healthcare Cardiology Hemodynamics™**Sep 11, 2023  
165 days to decisionK230881 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k230881/>**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	Mar 30, 2023
Decision date	Sep 11, 2023
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Change Healthcare Israel , Ltd.</b>
Location	Holon, IL
Contact	Alona Golik
510(k) history	3 submissions · 3 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230881/> 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 15, 2026