

**K232670 HiCardi+ H100**Sep 20, 2024  
385 days to decisionK232670 · Product code: **DSH** · CardiovascularSource: <https://www.510kdatabase.net/k232670/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 1, 2023
Decision date	Sep 20, 2024
Days to decision	385 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MEZOO Co., Ltd.</b>
Location	Wonju-Si, KR
Contact	Junghwan Park
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232670/> 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 13, 2026