

**K231596 IOB Temperature Management System**Jun 30, 2023  
29 days to decisionK231596 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k231596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jun 1, 2023
Decision date	Jun 30, 2023
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Iob Medical, Inc.</b>
Location	Gaithersburg, MD, US
Contact	Jonathan Kovach
510(k) history	7 submissions · 7 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231596/> 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 26, 2026