

**K252861 Warming System**Apr 7, 2026  
210 days to decisionK252861 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k252861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Sep 9, 2025
Decision date	Apr 7, 2026
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Tappa Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Na Ban
510(k) history	2 submissions · 2 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252861/> 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 14, 2026