

**K180375 The IQool™ Warm System**May 18, 2018  
95 days to decisionK180375 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k180375/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Feb 12, 2018
Decision date	May 18, 2018
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Braincool AB</b>
Location	Medicon Village, SE
Contact	Martin Waleij
510(k) history	4 submissions · 3 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180375/> 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