

K232844 The IQool™ SystemOct 4, 2023
20 days to decisionK232844 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k232844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Thermal Regulating (DWJ)
Date received	Sep 14, 2023
Decision date	Oct 4, 2023
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232844/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026