

K162523 The IQool SystemMay 3, 2017
236 days to decisionK162523 · Product code: **NZE** · Cardiovascular
Source: <https://www.510kdatabase.net/k162523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hyperthermia Monitor (NZE)
Date received	Sep 9, 2016
Decision date	May 3, 2017
Days to decision	236 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

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