

K181671 Cocoon Convective Warming SystemMay 2, 2019
311 days to decisionK181671 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k181671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Thermal Regulating (DWJ)
Date received	Jun 25, 2018
Decision date	May 2, 2019
Days to decision	311 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Care Essentials Pty, Ltd.
Location	Parkside, South Australia, AU
Contact	Abhay Sinha
510(k) history	4 submissions · 4 cleared · 2014-2024

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