

**K140635 COCOON CONVECTIVE WARMING SYSTEM**Jul 25, 2014  
135 days to decisionK140635 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k140635/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Mar 12, 2014
Decision date	Jul 25, 2014
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Care Essentials Pty, Ltd.</b>
Location	Parkside, South Australia, AU
Contact	BIBIANA FRANCO
510(k) history	4 submissions · 4 cleared · 2014-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140635/> 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 27, 2026