

K130300 HEATER-COOLER UNIT HCU 40Jul 1, 2013
144 days to decisionK130300 · Product code: **DWC** · Cardiovascular
Source: <https://www.510kdatabase.net/k130300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Feb 7, 2013
Decision date	Jul 1, 2013
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maquet Cardiopulmonary, AG
Location	Fairfield, IA, US
Contact	HELDER A SOUSA
510(k) history	44 submissions · 44 cleared · 2005-2015

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