

K031544 HEATER COOLER UNIT, MODEL HCU 30Aug 7, 2003
83 days to decisionK031544 · Product code: **DWC** · Cardiovascular
Source: <https://www.510kdatabase.net/k031544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	May 16, 2003
Decision date	Aug 7, 2003
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jostra AB
Location	The Woodlands, TX, US
Contact	LE ANN LATHAM
510(k) history	1 submissions · 1 cleared · 2003-2003

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