

K831677 HYPER-HYPOTHERMIA UNIT HYPO 10-200Jul 18, 1983
56 days to decisionK831677 · Product code: **DWC** · CardiovascularSource: <https://www.510kdatabase.net/k831677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	May 23, 1983
Decision date	Jul 18, 1983
Days to decision	56 days
Third-party review	No

APPLICANT

Company	Gambro, Inc.
Location	Mchenry, IL, US
510(k) history	86 submissions · 86 cleared · 1976-2009

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