

K133598 CARDIOHELP SYSTEMMay 21, 2014
180 days to decisionK133598 · Product code: **DTQ** · CardiovascularSource: <https://www.510kdatabase.net/k133598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Nov 22, 2013
Decision date	May 21, 2014
Days to decision	180 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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