

**K102919 NEONATAL VENOUS HARDSHELL CARDIOTOMY
RESERVOIR, PEDIATRIC VENOUS HARDSHELL CARSIOTOMY
RESERVOIR, NEONATAL VENOUS HARDSHE**Mar 11, 2011
161 days to decisionK102919 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k102919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Oct 1, 2010
Decision date	Mar 11, 2011
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102919/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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