

K132166 VENOUS HARDSHELL CARDIOTOMY RESERVOIROct 30, 2013
110 days to decisionK132166 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k132166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jul 12, 2013
Decision date	Oct 30, 2013
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary
Other names	NON-COATED, NON-TIGHT/ VACUUM-TIGHT/ WITH SOFTLINE COATING, VACUUM-TIGHT

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026