

**K003551 VENOUS HARDSHELL CARDIOTOMY RESEVOIR,
MODEL VHK 4201**Jul 11, 2001
236 days to decisionK003551 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k003551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Nov 17, 2000
Decision date	Jul 11, 2001
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jostra AG
Location	Newark, DE, US
Contact	KATHLEEN JOHNSON
510(k) history	13 submissions · 13 cleared · 2000-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003551/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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