

K241053 MVR™ Venous Reservoir Bag 800 mLMay 15, 2024
28 days to decisionK241053 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k241053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Apr 17, 2024
Decision date	May 15, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MVR™ Venous Reservoir Bag 1600 mL; MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 800 mL; MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 1600 mL

APPLICANT

Company	Medtronic Cardiac Surgery
Location	Mounds View, MN, US
Contact	Yidi Hou
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241053/> 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 May 14, 2026