

K223361 BMR 1900 PHISIOJun 10, 2023
219 days to decisionK223361 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k223361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Nov 3, 2022
Decision date	Jun 10, 2023
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Group Italia S.R.L.
Location	Mirandola, IT
Contact	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026

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