

K103168 B-CARE5 (B-CARE5 SENSOR MODULE, VENOUS SENSOR, HOLDER FOR MEASURING HEAD)Jan 6, 2011
71 days to decisionK103168 · Product code: **DRY** · Cardiovascular
Source: <https://www.510kdatabase.net/k103168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Oct 27, 2010
Decision date	Jan 6, 2011
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Group Deutschland GmbH
Location	North Attleboro, MA, US
Contact	ROSINA ROBINSON
510(k) history	20 submissions · 20 cleared · 2006-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103168/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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