

**K101046 STOCKERT S5 SYSTEM AND GAS BLENDER AND
SORIN C5 SYSTEM**Dec 9, 2010
239 days to decisionK101046 · Product code: **DTX** · Cardiovascular
Source: <https://www.510kdatabase.net/k101046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Control Unit, Cardiopulmonary Bypass (DTX)
Date received	Apr 14, 2010
Decision date	Dec 9, 2010
Days to decision	239 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/k101046/> 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 24, 2026