

**K963758 CODE 150 BLOOD COMPONENT COLLECTION SET  
AND WITH DIRECT DRAW LINE**

Feb 20, 1998  
520 days to decision

K963758 · Product code: **CAC** · Anesthesiology  
Source: <https://www.510kdatabase.net/k963758/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Sep 18, 1996
Decision date	Feb 20, 1998
Days to decision	520 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sorin Biomedical, Inc.</b>
Location	Irvine, CA, US
Contact	SUSAN J REIMERS
510(k) history	15 submissions · 15 cleared · 1993-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k963758/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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