

**K031194 SPIROSOFT**Jul 30, 2003  
105 days to decisionK031194 · Product code: **BTY** · Anesthesiology  
Source: <https://www.510kdatabase.net/k031194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Apr 16, 2003
Decision date	Jul 30, 2003
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Viasys Healthcare GmbH</b>
Location	Yorba Linda, CA, US
Contact	EARL DRAPER
510(k) history	14 submissions · 14 cleared · 2003-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031194/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026