

**K000881 PERFADEX SOLUTION FOR ORGAN PRESERVATION**Mar 8, 2001  
353 days to decisionK000881 · Product code: **MSB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k000881/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System And Accessories, Isolated Heart, Transport And Preservation (MSB)
Date received	Mar 20, 2000
Decision date	Mar 8, 2001
Days to decision	353 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitrolife Sweden AB</b>
Location	Ringoes, NJ, US
Contact	KARL A POSSELT
510(k) history	38 submissions · 38 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000881/> 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 June 28, 2026