

**K081997 PERFADEX WITH THAM**Oct 9, 2008  
87 days to decisionK081997 · Product code: **MSB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k081997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System And Accessories, Isolated Heart, Transport And Preservation (MSB)
Date received	Jul 14, 2008
Decision date	Oct 9, 2008
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitrolife Sweden AB</b>
Location	Ringoes, NJ, US
Contact	KJELL KJORK
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/k081997/> 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 24, 2026