

K091989 PERFADEX AND PERFADEX WITH THAMOct 1, 2010
456 days to decisionK091989 · Product code: **KDN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k091989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Perfusion, Kidney (KDN)
Date received	Jul 2, 2009
Decision date	Oct 1, 2010
Days to decision	456 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xvivo Perfusion AB
Location	Gutengurg, SE
Contact	KJELL KJORK
510(k) history	3 submissions · 3 cleared · 2010-2022

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