

K170826 Perfadex PlusJun 22, 2018
459 days to decisionK170826 · Product code: **KDN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k170826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Mar 20, 2017
Decision date	Jun 22, 2018
Days to decision	459 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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