

K261644 Perfadex Plus

Jul 23, 2026
66 days to decision

K261644 · Product code: **KDN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k261644/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	May 18, 2026
Decision date	Jul 23, 2026
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xvivo Perfusion AB
Location	Gutengurg, SE
Contact	Petra Rosen
510(k) history	4 submissions · 4 cleared · 2010-2026