FDA 510(k) Premarket Notification

K211333 KIDNEY ASSIST-transport

CLEARED

Jan 20, 2022
262 days to decision

K211333 · Product code: **KDN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k211333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	May 3, 2021
Decision date	Jan 20, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xvivo Perfusion AB**
Location	Gutengurg, SE
Contact	Arjan van der Plaats
510(k) history	3 submissions · 3 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**Medical Device Approvals, Inc.**
Contact	Kathleen Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov