FDA 510(k) Premarket Notification

K240650 LungProtect

CLEARED

Nov 26, 2024
264 days to decision

K240650 · Product code: **KDN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Mar 7, 2024
Decision date	Nov 26, 2024
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Traferox Technologies, Inc.**
Location	Mississauga, CA
Contact	Nicole Baker
510(k) history	2 submissions · 2 cleared · 2024-2025