FDA 510(k) Premarket Notification

K232761 ProNephro AKI™ (NGAL)

CLEARED

Dec 7, 2023
90 days to decision

K232761 · Product code: **PIG** · Chemistry
Source: https://www.510kdatabase.net/k232761/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acute Kidney Injury Test System (PIG)
Date received	Sep 8, 2023
Decision date	Dec 7, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bioporto Diagnostic, Inc.**
Location	Needham, MA, US
Contact	Asger Dahlgaard
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Bioporto Diagnostics A/S**
Contact	Monika Bak

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