

K232761 ProNephro AKI™ (NGAL)Dec 7, 2023
90 days to decisionK232761 · 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

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