

K971825 PANCREATIC AMYLASE, ETHYLIDENE BLOCKED-PNPG7 ENZYME COLORIMETRIC TESTJul 24, 1997
69 days to decisionK971825 · Product code: JFJ · Chemistry
Source: <https://www.510kdatabase.net/k971825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	May 16, 1997
Decision date	Jul 24, 1997
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Randox Laboratories, Ltd.
Location	Antrim, N. Ireland, IR
Contact	PONE ARMSTRONG
Website	http://www.randox.com/
510(k) history	116 submissions · 115 cleared · 1992-2025

Randox Laboratories, Ltd. is a global diagnostic company specializing in chemistry devices and laboratory solutions. The company operates with a manufacturing facility in Antrim, Northern Ireland, and has over 40 years of expertise in diagnostic innovation. Randox has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's regulatory portfolio is dominated by chemistry devices, including clinical chemistry analyzers, reagents, controls, and electrodes. The latest clearance on record dates to 2023. Recent FDA 510(k) cleared de...

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