FDA 510(k) Premarket Notification

CLEARED

K972220 RHEUMATOID FACTOR LATEX-ENHANCED IMMUNOTURBIDIMETRIC TEST KIT

Sep 9, 1997
89 days to decision

K972220 · Product code: **DHR** · Immunology
Source: https://www.510kdatabase.net/k972220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Jun 12, 1997
Decision date	Sep 9, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Randox Laboratories, Ltd.**
Location	Antrim, N. Ireland, IR
Contact	P. 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...