FDA 510(k) Premarket Notification

CLEARED

K012319 RANDOX HUMAN ASSSAYED DRUG CONTROL

Aug 24, 2001
32 days to decision

K012319 · Product code: **DIF** · Chemistry
Source: https://www.510kdatabase.net/k012319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jul 23, 2001
Decision date	Aug 24, 2001
Days to decision	32 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...