FDA 510(k) Premarket Notification

K012112 RANDOX DIGITOXIN

CLEARED

Jan 11, 2002
189 days to decision

K012112 · Product code: **LFM** · Toxicology
Source: https://www.510kdatabase.net/k012112/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digitoxin (LFM)
Date received	Jul 6, 2001
Decision date	Jan 11, 2002
Days to decision	189 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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