

**K953210 GLUCOSE (HEXOKINASE) KIT**Oct 25, 1996  
473 days to decisionK953210 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k953210/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jul 10, 1995
Decision date	Oct 25, 1996
Days to decision	473 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Randox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	John Lamont
Website	<a href="http://www.randox.com/">http://www.randox.com/</a>
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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