

K223324 Total Bilirubin2Dec 29, 2022
59 days to decisionK223324 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k223324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Oct 31, 2022
Decision date	Dec 29, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Ireland Diagnostics Division
Location	Longford, IE
Contact	Magdalena Suszko
510(k) history	8 submissions · 8 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223324/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026