

K203771 Urea Nitrogen2May 31, 2022
524 days to decisionK203771 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k203771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Dec 23, 2020
Decision date	May 31, 2022
Days to decision	524 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203771/> 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