

**K220977 ISE Reagents, Glucose, CRP Latex, DxC 500 AU
Clinical Chemistry Analyzer**Jul 20, 2023
472 days to decisionK220977 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k220977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	Apr 4, 2022
Decision date	Jul 20, 2023
Days to decision	472 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter Laboratory Systems (Suzhou) Co., Ltd.
Location	Suzhou, CN
Contact	Tracy Jin
510(k) history	2 submissions · 2 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220977/>. 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