

**K250073 Tosoh Automated Glycohemoglobin Analyzer
HLC-723GR01**

Oct 3, 2025
266 days to decision

K250073 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k250073/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Jan 10, 2025
Decision date	Oct 3, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tosoh Bioscience, Inc.
Location	Grove City, OH, US
Contact	Corike Nuibe
510(k) history	20 submissions · 20 cleared · 2007-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k250073/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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