

**K131580 AUTOMATED GYLCOHEMOGLOBIN ANALYZER
HLC-723G8**Jan 23, 2014
237 days to decisionK131580 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k131580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	May 31, 2013
Decision date	Jan 23, 2014
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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