

**K200904 Tosoh Automated Glycohemoglobin Analyzer
HLC-723G8**Aug 5, 2021
486 days to decisionK200904 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k200904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Apr 6, 2020
Decision date	Aug 5, 2021
Days to decision	486 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	Louise Musante
510(k) history	20 submissions · 20 cleared · 2007-2025

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