

K252749 Medconn 8K Glycated Hemoglobin Test SystemJan 6, 2026
130 days to decisionK252749 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k252749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Aug 29, 2025
Decision date	Jan 6, 2026
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Medconn Medical Technology Co., Ltd.
Location	Shanghai, CN
Contact	Judan Guan
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Guangdong Grzan Group Co., Ltd.
Contact	Jessie Mu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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