

**K242911 Medconn Glycated Hemoglobin Test system**Jun 20, 2025  
269 days to decisionK242911 · Product code: **PDJ** · Chemistry  
Source: <https://www.510kdatabase.net/k242911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Sep 24, 2024
Decision date	Jun 20, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangdong Grzan Group Co., Ltd.</b>
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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