

**K220999 Hipro Glycosylated Hemoglobin (HbA1c) Test System**Sep 12, 2024  
892 days to decisionK220999 · Product code: **PDJ** · Chemistry  
Source: <https://www.510kdatabase.net/k220999/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Hemoglobin A1c Test System (PDJ)   |
| Date received         | Apr 4, 2022                        |
| Decision date         | Sep 12, 2024                       |
| Days to decision      | 892 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shijiazhuang Hipro Biotechnology Co., Ltd.</b> |
| Location       | Shijiazhuang, CN                                  |
| Contact        | Emily No Last Name Provided                       |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024             |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Shenzhen Joyantech Consulting Co., Ltd.</b> |
| Contact         | Hanson Chen                                    |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220999/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026