

K250205 Babio® Virus Transport Kit (Non-inactivating)Sep 22, 2025
241 days to decisionK250205 · Product code: **JSM** · Microbiology
Source: <https://www.510kdatabase.net/k250205/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Culture Media, Non-propagating Transport (JSM) |
| Date received | Jan 24, 2025 |
| Decision date | Sep 22, 2025 |
| Days to decision | 241 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Jinan Babio Biotechnology Co., Ltd. |
| Location | Jinan, CN |
| Contact | Xiaotong Zhou |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------|
| Consulting firm | Iyou Health |
| Contact | Keqin Gregg |

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.netDevice record: <https://www.510kdatabase.net/k250205/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026