

**K153050 Rapid Single/Multi-drug Test Cup, Rapid Single/Multi-drug Test Dipcard**Apr 26, 2016  
189 days to decisionK153050 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k153050/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Enzyme Immunoassay, Opiates (DJG)  |
| Date received         | Oct 20, 2015                       |
| Decision date         | Apr 26, 2016                       |
| Days to decision      | 189 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Co-Innovation Biotech Co., Ltd.</b>  |
| Location       | Guangzhou, Guangdong, CN                |
| Contact        | Hong Feng                               |
| 510(k) history | 10 submissions · 10 cleared · 2013-2024 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153050/> 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 26, 2026