

**K232736 Chemtrue® Drug Screen Fentanyl/Tramadol Cup Test,  
Chemtrue® Drug Screen Fentanyl/Tramadol Dip Card Test,  
Chemtrue® Multi-Panel Drug Screen Cup Test, Chemtrue® Multi-  
Panel Drug Screen Dip Card Test**Dec 20, 2023  
104 days to decisionK232736 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k232736/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Enzyme Immunoassay, Opiates (DJG)  |
| Date received         | Sep 7, 2023                        |
| Decision date         | Dec 20, 2023                       |
| Days to decision      | 104 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Chemtron Biotech, Inc.</b>           |
| Location       | San Diego, CA, US                       |
| Contact        | Jane Zhang                              |
| 510(k) history | 11 submissions · 11 cleared · 2011-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232736/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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