

K150502 DRI Hydrocodone Assay, DRI Hydrocodone Calibrators, DRI Hydrocodone ControlsOct 9, 2015
225 days to decisionK150502 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k150502/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Opiates (DJG) |
| Date received | Feb 26, 2015 |
| Decision date | Oct 9, 2015 |
| Days to decision | 225 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Microgenics Corporation |
| Location | Fremont Blvd., CA, US |
| Contact | Tammy Wharton |
| 510(k) history | 21 submissions · 20 cleared · 2009-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150502/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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