

**K973156 UBI MAGIWEL COCAINE METABOLITES**Oct 28, 1997  
67 days to decisionK973156 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k973156/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Enzyme Immunoassay, Opiates (DJG)  |
| Date received         | Aug 22, 1997                       |
| Decision date         | Oct 28, 1997                       |
| Days to decision      | 67 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>United Biotech, Inc.</b>             |
| Location       | Mountain View, CA, US                   |
| Contact        | WUAN T LU                               |
| 510(k) history | 22 submissions · 22 cleared · 1985-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973156/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026