

**K002337 BRANAN MEDICAL CORPORATION MONITECT  
BARBITURATES DRUG SCREEN TEST**Nov 22, 2000  
113 days to decisionK002337 · Product code: **DIS** · Toxicology  
Source: <https://www.510kdatabase.net/k002337/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Enzyme Immunoassay, Barbiturate (DIS) |
| Date received         | Aug 1, 2000                           |
| Decision date         | Nov 22, 2000                          |
| Days to decision      | 113 days                              |
| Third-party review    | No                                    |
| Summary / Statement   | Statement                             |

**APPLICANT**

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|----------------|---|
| Company        | <b>Branan Medical Corporation</b>       |
| Location       | Irvine, CA, US                          |
| Contact        | RAPHAEL WONG                            |
| 510(k) history | 11 submissions · 11 cleared · 2000-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002337/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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