

K003647 INSTANT-VIEW BARBITURATE URINE CASSETTE TESTMay 29, 2001
183 days to decisionK003647 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k003647/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Barbiturate (DIS) |
| Date received | Nov 27, 2000 |
| Decision date | May 29, 2001 |
| Days to decision | 183 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Alfa Scientific Designs, Inc. |
| Location | Poway, CA, US |
| Contact | NAISHU WANG |
| 510(k) history | 43 submissions · 43 cleared · 1999-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003647/>; 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 June 28, 2026