

K011499 VISUALINE AMPHETAMINE DIPSTRIP ASSAYJul 17, 2001
63 days to decisionK011499 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k011499/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Amphetamine (DKZ) |
| Date received | May 15, 2001 |
| Decision date | Jul 17, 2001 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Sun Biomedical Laboratories, Inc. |
| Location | Cherry Hill, NJ, US |
| Contact | MING SUN |
| 510(k) history | 17 submissions · 17 cleared · 1994-2003 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011499/> 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