

K020395 AMPHETAMINES ENZYME IMMUNOASSAY, CATALOG #0040 (500 TESTS KIT), CATALOG #0041 (5000 TESTS KIT)

Jun 4, 2002
118 days to decision

K020395 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k020395/>

SUBMISSION DETAILS

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Amphetamine (DKZ) |
| Date received | Feb 6, 2002 |
| Decision date | Jun 4, 2002 |
| Days to decision | 118 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Lin-Zhi International, Inc. |
| Location | San Jose, CA, US |
| Contact | CHIU CHIN CHANG |
| 510(k) history | 50 submissions · 49 cleared · 2002-2026 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k020395/> 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