

**K010177 VISUALINE II (ALSO KNOWN AS SUNLINE)  
AMPHETAMINE ASSAY**May 17, 2001  
119 days to decisionK010177 · Product code: **DKZ** · Toxicology  
Source: <https://www.510kdatabase.net/k010177/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jan 18, 2001
Decision date	May 17, 2001
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010177/>. 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