

**K980120 DIGENE DML 2000 MICROPLATE LUMINOMETER**Feb 6, 1998  
24 days to decisionK980120 · Product code: **JJQ** · Chemistry  
Source: <https://www.510kdatabase.net/k980120/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Jan 13, 1998
Decision date	Feb 6, 1998
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Digene Corp.</b>
Location	Gaithersburg, MD, US
Contact	CONSTANCE A FINCH
510(k) history	9 submissions · 9 cleared · 1997-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980120/> 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 29, 2026