

**K940486 DIGENE DCR-1 LUMINOMETER**Apr 18, 1995  
440 days to decisionK940486 · Product code: **JJQ** · Microbiology  
Source: <https://www.510kdatabase.net/k940486/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Feb 2, 1994
Decision date	Apr 18, 1995
Days to decision	440 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Digene Diagnostics, Inc.</b>
Location	Silver Spring, MD, US
Contact	CHARLES M FLEISCHMAN
510(k) history	1 submissions · 1 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940486/> 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