

**K981567 HYBRID CAPTURE II CT/GC TEST**Feb 29, 2000  
669 days to decisionK981567 · Product code: **LSL** · Microbiology  
Source: <https://www.510kdatabase.net/k981567/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	May 1, 1998
Decision date	Feb 29, 2000
Days to decision	669 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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