

**K010891 MODIFICATION TO HYBRID CAPTURE II CT/GC TEST,  
MODEL 03M90-01**Sep 25, 2001  
183 days to decisionK010891 · Product code: **LSK** · Microbiology  
Source: <https://www.510kdatabase.net/k010891/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Chlamydia (LSK)
Date received	Mar 26, 2001
Decision date	Sep 25, 2001
Days to decision	183 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010891/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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