

K990023 HYBRID CAPTURE II CT-ID TESTOct 25, 1999
293 days to decisionK990023 · Product code: **LSK** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Chlamydia (LSK)
Date received	Jan 5, 1999
Decision date	Oct 25, 1999
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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