

K981485 HYBRID CAPTURE II GC-IDNov 29, 1999
584 days to decisionK981485 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k981485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Apr 24, 1998
Decision date	Nov 29, 1999
Days to decision	584 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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