

K010893 MODIFICATION TO HYBRID CAPTURE 2 GC-ID DNA TEST, MODEL 03M92-01

Sep 24, 2001
182 days to decision

K010893 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k010893/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Mar 26, 2001
Decision date	Sep 24, 2001
Days to decision	182 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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Device record: <https://www.510kdatabase.net/k010893/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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