FDA 510(k) Premarket Notification

K010891 MODIFICATION TO HYBRID CAPTURE II CT/GC TEST, MODEL 03M90-01

CLEARED

Sep 25, 2001
183 days to decision

K010891 · Product code: **LSK** · Microbiology
Source: https://www.510kdatabase.net/k010891/

SUBMISSION DETAILS

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

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