FDA 510(k) Premarket Notification

K990023 HYBRID CAPTURE II CT-ID TEST

CLEARED

Oct 25, 1999
293 days to decision

K990023 · Product code: **LSK** · Microbiology
Source: https://www.510kdatabase.net/k990023/

SUBMISSION DETAILS

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