FDA 510(k) Premarket Notification

K081824 BD PROBETEC CHLAMYDIA TRACHOMATIS (CT) Q AMPLIFIED DNA ASSAY

CLEARED

Dec 11, 2008
167 days to decision

K081824 · Product code: **MKZ** · Microbiology
Source: https://www.510kdatabase.net/k081824/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ)
Date received	Jun 27, 2008
Decision date	Dec 11, 2008
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson & CO**
Location	Franklin Lakes, NJ, US
Contact	KATHRYN B CARR
510(k) history	190 submissions · 190 cleared · 2001-2016