

K971170 CAMBRIDGE BIOTECH HUMAN LYME IGM WESTERN BLOT (90112)Feb 17, 1998
326 days to decisionK971170 · Product code: **LSR** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 28, 1997
Decision date	Feb 17, 1998
Days to decision	326 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cambridge Biotech Corp.
Location	Worcester, MA, US
Contact	REBECCA LEAPER
510(k) history	3 submissions · 3 cleared · 1991-1998

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