

K970768 HUMAN LYME IGM WESTERN BLOT KITApr 9, 1998
402 days to decisionK970768 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k970768/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 3, 1997
Decision date	Apr 9, 1998
Days to decision	402 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cambridge Diagnostics Ireland, Ltd.
Location	Galway, IE
Contact	SILE MACMAHON
510(k) history	4 submissions · 4 cleared · 1996-2001

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