

**K970761 LIMITED HUMAN LYME IGG WESTERN BLOT KIT  
(CAMBRIDGE DIAGNOSTICS IRELAND)**

Apr 9, 1998  
402 days to decision

K970761 · Product code: LSR · Microbiology  
Source: <https://www.510kdatabase.net/k970761/>

**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k970761/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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