

**K946353 EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN  
RECOMBINANT IMMUNOFLUORESCENT ASSAY**Jul 21, 1995  
203 days to decisionK946353 · Product code: **LLM** · Microbiology  
Source: <https://www.510kdatabase.net/k946353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Dec 30, 1994
Decision date	Jul 21, 1995
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MrI Diagnostics</b>
Location	Cypress, CA, US
Contact	Bill Hyatt
510(k) history	7 submissions · 7 cleared · 1994-2000

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