

**K894626 EPSTEIN-BARR VIRUS-NUCLEAR ANTIGEN**Oct 16, 1989  
88 days to decisionK894626 · Product code: **LLM** · Microbiology  
Source: <https://www.510kdatabase.net/k894626/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Jul 20, 1989
Decision date	Oct 16, 1989
Days to decision	88 days
Third-party review	No

**APPLICANT**

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Company	<b>Bion Ent., Ltd.</b>
Location	Mchenry, IL, US
Contact	JUDY MCCORMACK
510(k) history	14 submissions · 14 cleared · 1980-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894626/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026