

**K894623 RESPIRATORY SYNCYTIAL VIRUS**Oct 16, 1989  
88 days to decisionK894623 · Product code: **LKT** · Microbiology  
Source: <https://www.510kdatabase.net/k894623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus, Antigen, Antibody, Ifa (LKT)
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/k894623/>; 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