

**K861016 GAMMA SLIDE TEST FOR INFECTIOUS MONONUCLEOSIS**Apr 18, 1986  
31 days to decisionK861016 · Product code: **KTN** · Immunology  
Source: <https://www.510kdatabase.net/k861016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Mar 18, 1986
Decision date	Apr 18, 1986
Days to decision	31 days
Third-party review	No

**APPLICANT**

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Company	<b>Gamma Biologicals, Inc.</b>
Location	Mchenry, IL, US
Contact	JOHN CASE
510(k) history	21 submissions · 21 cleared · 1976-1986

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861016/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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