

**K864207 DISPOSABLE TEST CARDS/GAMMA SLIDE TEST
INFECT MONO**Dec 3, 1986
37 days to decisionK864207 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k864207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Oct 27, 1986
Decision date	Dec 3, 1986
Days to decision	37 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864207/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026