

K883306 BINAS LUTEINIZING HORMONE IRMA TEST KITOct 6, 1988
63 days to decisionK883306 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k883306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Aug 4, 1988
Decision date	Oct 6, 1988
Days to decision	63 days
Third-party review	No

APPLICANT

Company	Binax, Inc.
Location	S. Portland, ME, US
Contact	BRUCE F WATKINS
510(k) history	30 submissions · 30 cleared · 1986-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883306/>; 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 21, 2026