

K954901 BIONIKE A/Q PREGNANCY TESTDec 11, 1995
47 days to decisionK954901 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k954901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 25, 1995
Decision date	Dec 11, 1995
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bionike Laboratories, Inc.
Location	Sunnyvale, CA, US
Contact	JANIS FREESTONE
510(k) history	6 submissions · 6 cleared · 1995-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954901/> 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 28, 2026