

K970008 ADVANCED QUALITY PREGNANCY TESTFeb 18, 1997
47 days to decisionK970008 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k970008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jan 2, 1997
Decision date	Feb 18, 1997
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bionike, Inc.
Location	South San Francisco, CA, US
Contact	JANIS FREESTONE
510(k) history	2 submissions · 2 cleared · 1997-1999

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