

K042280 FACT PLUS ONE-STEP PREGNANCY TEST KITSep 10, 2004
18 days to decisionK042280 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k042280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 23, 2004
Decision date	Sep 10, 2004
Days to decision	18 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Unipath , Ltd.
Location	Bedford Mk41 Oqg, GB
Contact	Louise Roberts
510(k) history	73 submissions · 73 cleared · 1986-2006

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