FDA 510(k) Premarket Notification

K822449 TPK 1980/1

CLEARED

Oct 27, 1982
72 days to decision

K822449 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k822449/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 16, 1982
Decision date	Oct 27, 1982
Days to decision	72 days
Third-party review	No

APPLICANT

Company	**Plantex USA, Inc.**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1982-1982