FDA 510(k) Premarket Notification

K921968 IN VITRO DIAGNOSTIC REAGENT SET, INDIR. PREG. TEST

CLEARED

Jun 28, 1996
1523 days to decision

K921968 · Product code: **JHJ** · Chemistry
Source: https://www.510kdatabase.net/k921968/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Apr 27, 1992
Decision date	Jun 28, 1996
Days to decision	1523 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Tech-Co, Inc.**
Location	Troy, MI, US
Contact	K. C CHEN
510(k) history	36 submissions · 36 cleared · 1986-1996