FDA 510(k) Premarket Notification

K802334 IN-HOME EARLY PREGNANCY TEST KIT

CLEARED

Oct 10, 1980
17 days to decision

K802334 · Product code: **JHJ** · Chemistry
Source: https://www.510kdatabase.net/k802334/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Sep 23, 1980
Decision date	Oct 10, 1980
Days to decision	17 days
Third-party review	No

APPLICANT

Company	**Health Diagnostics Corp.**
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1980-1980