

**K914696 MEDIX BIOTECH TOTAL HCG ENZY IMMUN TEST KT  
DIF4011**Nov 13, 1991  
26 days to decisionK914696 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k914696/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 18, 1991
Decision date	Nov 13, 1991
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Medix Biotech, Inc.</b>
Location	Redwood City, CA, US
Contact	JOHN CHEN
510(k) history	39 submissions · 39 cleared · 1985-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914696/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026