

**K041728 HCG DETECTOR COMBI, HCG DETECTOR STIX, HCG  
DETECTOR CASSETTE**Aug 11, 2004  
47 days to decisionK041728 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k041728/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jun 25, 2004
Decision date	Aug 11, 2004
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Immunostics Inc.,</b>
Location	Ocean, NJ, US
Contact	JEFFREY FLEISHMAN
510(k) history	14 submissions · 14 cleared · 1997-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041728/> 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 May 26, 2026