

K981443 BIOSIGN HCG I - ONE STEP PREGNANCY TESTJun 25, 1998
64 days to decisionK981443 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k981443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 22, 1998
Decision date	Jun 25, 1998
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	JEMO KANG
510(k) history	72 submissions · 72 cleared · 1994-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981443/> 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 25, 2026