

K954065 BIODATA SR1 FAH-HCG ENZYME IMMUNOASSAY KITJul 10, 1996
315 days to decisionK954065 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k954065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 30, 1995
Decision date	Jul 10, 1996
Days to decision	315 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biochem Immunosystems (U.S.), Inc.
Location	Allentown, PA, US
Contact	LAURENCE A POTTER
510(k) history	4 submissions · 4 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954065/> 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 28, 2026