

K841525 OREIA II B-HCG PREGNANCY TEST KITJun 5, 1984
54 days to decisionK841525 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k841525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 12, 1984
Decision date	Jun 5, 1984
Days to decision	54 days
Third-party review	No

APPLICANT

Company	Organon, Inc.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1977-1995

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k841525/> 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