

K832801 OREIA II B-HCG, ENZYME INNUNOASSAYDec 8, 1983
112 days to decisionK832801 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k832801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 18, 1983
Decision date	Dec 8, 1983
Days to decision	112 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/k832801/> 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