

K830997 ARIA II I-HCGJun 2, 1983
65 days to decisionK830997 · Product code: **JHI** · Immunology
Source: <https://www.510kdatabase.net/k830997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 29, 1983
Decision date	Jun 2, 1983
Days to decision	65 days
Third-party review	No

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
510(k) history	632 submissions · 625 cleared · 1976-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k830997/> 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 21, 2026