

**K830203 DAC-CEL DIAGNATAL RD 50**Feb 18, 1983  
29 days to decisionK830203 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k830203/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jan 20, 1983
Decision date	Feb 18, 1983
Days to decision	29 days
Third-party review	No

**APPLICANT**

---

Company	<b>Wellcome Diagnostics</b>
Location	Walker, MI, US
510(k) history	28 submissions · 28 cleared · 1983-1992

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k830203/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026