

K830204 DAC-CEL DIAGNATAL HCG STANDARDS RD49Feb 18, 1983
29 days to decisionK830204 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k830204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 20, 1983
Decision date	Feb 18, 1983
Days to decision	29 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k830204/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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