

**K831073 DAC-CEL HCG-MCA KIT RD52**Sep 1, 1983  
150 days to decisionK831073 · Product code: **CFL** · Chemistry  
Source: <https://www.510kdatabase.net/k831073/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Radioimmunoassay, Human Growth Hormone (CFL) |
| Date received         | Apr 4, 1983                                  |
| Decision date         | Sep 1, 1983                                  |
| Days to decision      | 150 days                                     |
| Third-party review    | No   |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k831073/> 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