

**K830962 IMMUCHEM COVALENT-COAT RIA KIT**May 4, 1983  
37 days to decisionK830962 · Product code: **DPO** · Chemistry  
Source: <https://www.510kdatabase.net/k830962/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Radioimmunoassay, Digoxin (125-i), Rabbit Antibody, Coated Tube Sep. (DPO) |
| Date received         | Mar 28, 1983   |
| Decision date         | May 4, 1983  |
| Days to decision      | 37 days  |
| Third-party review    | No   |

**APPLICANT**

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| Company        | <b>Immucem Corp.</b>                    |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 18 submissions · 18 cleared · 1979-1988 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k830962/> 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 July 3, 2026