

**K823353 CARCINO-CEK**Dec 14, 1982  
35 days to decisionK823353 · Product code: **JJX** · Immunology  
Source: <https://www.510kdatabase.net/k823353/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received         | Nov 9, 1982   |
| Decision date         | Dec 14, 1982  |
| Days to decision      | 35 days   |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Biologics Intl., Inc.</b>          |
| Location       | Mchenry, IL, US                       |
| 510(k) history | 9 submissions · 9 cleared · 1979-1988 |

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

Device record: <https://www.510kdatabase.net/k823353/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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