

**K771255 CEBTRIA DIGOXIN RIA**Aug 25, 1977  
44 days to decisionK771255 · Product code: **DON** · Toxicology  
Source: <https://www.510kdatabase.net/k771255/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Radioimmunoassay, Digoxin (125-i), Rabbit Antibody, Solid Phase Sep. (DON) |
| Date received         | Jul 12, 1977   |
| Decision date         | Aug 25, 1977   |
| Days to decision      | 44 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Union Carbide Corp.</b>  |
| Location       | Mchenry, IL, US   |
| Website        | <a href="https://www.unioncarbide.com/en-us.html">https://www.unioncarbide.com/en-us.html</a> |
| 510(k) history | 69 submissions · 69 cleared · 1976-1983   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k771255/>; 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 May 22, 2026