

**K905719 ECLIPSE ICA DIGOXIN**Jan 17, 1991  
27 days to decisionK905719 · Product code: **DPO** · Toxicology  
Source: <https://www.510kdatabase.net/k905719/>**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	Dec 21, 1990
Decision date	Jan 17, 1991
Days to decision	27 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotope, Inc.</b>
Location	Redmond, WA, US
Contact	LYNN SHANTA
510(k) history	7 submissions · 7 cleared · 1991-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905719/>; 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