

**K905602 ECLIPSE ICA BUN**Jan 16, 1991  
34 days to decisionK905602 · Product code: **CDQ** · Chemistry  
Source: <https://www.510kdatabase.net/k905602/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Dec 13, 1990
Decision date	Jan 16, 1991
Days to decision	34 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/k905602/>; 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