

**K905145 ECLIPSE ICA CHOLESTEROL**Feb 26, 1991  
103 days to decisionK905145 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k905145/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Nov 15, 1990
Decision date	Feb 26, 1991
Days to decision	103 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905145/>; 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