

**K011970 BIOSAFE CHOLESTEROL PROFILE BLOOD  
COLLECTION AND TRANSPORT SYSTEM**Sep 26, 2001  
93 days to decisionK011970 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k011970/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Jun 25, 2001
Decision date	Sep 26, 2001
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosafe Laboratories, Inc.</b>
Location	Lake Forest, IL, US
Contact	JACK A MAGGIORE
510(k) history	6 submissions · 6 cleared · 1999-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011970/>, 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 28, 2026