

**K971072 CHOLESTEROL REAGENT**Jun 20, 1997  
88 days to decisionK971072 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k971072/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Mar 24, 1997
Decision date	Jun 20, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Derma Media Lab., Inc.</b>
Location	Santa Fe Springs, CA, US
Contact	CHARLES C ALLAIN
510(k) history	18 submissions · 18 cleared · 1996-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971072/> 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 30, 2026