

K792319 COULTER HDL CHOLESTEROL REAG. SYSTEMDec 6, 1979
17 days to decisionK792319 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k792319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Nov 19, 1979
Decision date	Dec 6, 1979
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Coulter Electronics, Inc.
Location	Mchenry, IL, US
510(k) history	101 submissions · 101 cleared · 1976-1994

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k792319/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026