

K791640 COULTER ACCU-ZYME II ENZYMATIC REAGENTSep 24, 1979
34 days to decisionK791640 · Product code: **CDT** · Chemistry
Source: <https://www.510kdatabase.net/k791640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Aug 21, 1979
Decision date	Sep 24, 1979
Days to decision	34 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k791640/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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