

K841471 ULTRA CHEM ENZYMATIC TRIGLYCERIDEMay 16, 1984
37 days to decisionK841471 · Product code: **CDT** · Chemistry
Source: <https://www.510kdatabase.net/k841471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Apr 9, 1984
Decision date	May 16, 1984
Days to decision	37 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
510(k) history	288 submissions · 288 cleared · 1984-1994

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Device record: <https://www.510kdatabase.net/k841471/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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