

K963424 OLYMPUS LIPASE REAGENTJan 14, 1997
137 days to decisionK963424 · Product code: **CDT** · Chemistry
Source: <https://www.510kdatabase.net/k963424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Aug 30, 1996
Decision date	Jan 14, 1997
Days to decision	137 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	LAURA STORMS-TYLER
510(k) history	149 submissions · 149 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963424/> 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 18, 2026