

K010871 TGL FLEX REAGENT CARTRIDGEJul 9, 2001
108 days to decisionK010871 · Product code: **CDT** · Chemistry
Source: <https://www.510kdatabase.net/k010871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Mar 23, 2001
Decision date	Jul 9, 2001
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	DONNA A WOLF
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010871/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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