FDA 510(k) Premarket Notification

K780379 DATA-ZYME TRIGLYCERIDE PROCEDURE

CLEARED

May 12, 1978
65 days to decision

K780379 · Product code: **CDT** · Chemistry
Source: https://www.510kdatabase.net/k780379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Mar 8, 1978
Decision date	May 12, 1978
Days to decision	65 days
Third-party review	No

APPLICANT

Company	**Data Medical Associates, Inc.**
Location	Mchenry, IL, US
510(k) history	111 submissions · 111 cleared · 1978-1999

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k780379/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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