FDA 510(k) Premarket Notification

K802842 SINGLE VIAL LIPASE TEST KIT

CLEARED

Dec 18, 1980
36 days to decision

K802842 · Product code: **CHI** · Chemistry
Source: https://www.510kdatabase.net/k802842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase-esterase, Enzymatic, Photometric, Lipase (CHI)
Date received	Nov 12, 1980
Decision date	Dec 18, 1980
Days to decision	36 days
Third-party review	No

APPLICANT

Company	**Biodynamics Corp.**
Location	Walker, MI, US
510(k) history	21 submissions · 21 cleared · 1980-2006

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k802842/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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