

K020575 ATAC DIRECT LDL REAGENT AND ATAC DIRECT LDL CALIBRATOR KITSApr 12, 2002
50 days to decisionK020575 · Product code: MRR · Chemistry
Source: <https://www.510kdatabase.net/k020575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Feb 21, 2002
Decision date	Apr 12, 2002
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elan Diagnostics
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	13 submissions · 13 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020575/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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