

K991789 ATAC-PAK DIRECT HDL CHOLESTEROL REAGENT AND ATAC HDL-C CALIBRATOR KITS

Jul 9, 1999
45 days to decision

K991789 · Product code: LBR · Chemistry
Source: <https://www.510kdatabase.net/k991789/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	May 25, 1999
Decision date	Jul 9, 1999
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elan Holdings, Inc.
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	12 submissions · 12 cleared · 1999-2001

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Device record: <https://www.510kdatabase.net/k991789/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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