

**K000958 ATAC PAK BUN REAGENT AND ATAC CALIBRATOR
KITS**May 24, 2000
61 days to decisionK000958 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k000958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Mar 24, 2000
Decision date	May 24, 2000
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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