

K021385 ATAC PAK BUN REAGENTJul 12, 2002
71 days to decisionK021385 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k021385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	May 2, 2002
Decision date	Jul 12, 2002
Days to decision	71 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

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