

K960115 HICHEM BUN/UREA REAGENT KITMar 29, 1996
78 days to decisionK960115 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k960115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Jan 11, 1996
Decision date	Mar 29, 1996
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elan Pharma, Inc.
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	4 submissions · 4 cleared · 1996-1998

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