

K040973 BUN REAGENTDec 27, 2004
257 days to decisionK040973 · Product code: **CDS** · Chemistry
Source: <https://www.510kdatabase.net/k040973/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Urea Nitrogen (CDS)
Date received	Apr 14, 2004
Decision date	Dec 27, 2004
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genchem, Inc.
Location	Brea, CA, US
Contact	C.C. ALLAIN
510(k) history	8 submissions · 8 cleared · 2004-2009

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