

K934533 BUN-300/BUN-500 UREA NITROGEN REAGENTNov 26, 1993
70 days to decisionK934533 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k934533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Sep 17, 1993
Decision date	Nov 26, 1993
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Horizon Diagnostics, Inc.
Location	Jackson, MI, US
Contact	P. R. PATEL
510(k) history	7 submissions · 7 cleared · 1993-1997

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