

K932161 UREA NITROGEN TEST ITEM NUMBER 65408Sep 8, 1993
127 days to decisionK932161 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k932161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	May 4, 1993
Decision date	Sep 8, 1993
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	CAROL FAULKNER
510(k) history	288 submissions · 288 cleared · 1984-1994

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