

**K961196 EKTACHEM CLINICAL CHEMISTRY UREA
NITROGEN/UREA (BUN/UREA)**May 15, 1996
49 days to decisionK961196 · Product code: **CDN** · Chemistry
Source: <https://www.510kdatabase.net/k961196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease, Photometric, Urea Nitrogen (CDN)
Date received	Mar 27, 1996
Decision date	May 15, 1996
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Johnson & Johnson Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	CHARLES C MORGANSON
510(k) history	33 submissions · 33 cleared · 1995-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961196/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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