

K800341 BUN REAGENTMar 12, 1980
26 days to decisionK800341 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k800341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Feb 15, 1980
Decision date	Mar 12, 1980
Days to decision	26 days
Third-party review	No

APPLICANT

Company	Gilford Diagnostics
Location	Mchenry, IL, US
510(k) history	50 submissions · 50 cleared · 1978-1983

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k800341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026