

K944250 UREA NITROGEN REAGENTFeb 8, 1995
160 days to decisionK944250 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k944250/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ) |
| Date received | Sep 1, 1994 |
| Decision date | Feb 8, 1995 |
| Days to decision | 160 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Olympus Corp of America |
| Location | Lake Success, NY, US |
| Contact | LAURA S TYLER |
| 510(k) history | 2 submissions · 2 cleared · 1995-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944250/> 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 July 1, 2026