

**K821212 UREA NITROGEN REAGENT SET**Jul 22, 1982  
86 days to decisionK821212 · Product code: **CDW** · Chemistry  
Source: <https://www.510kdatabase.net/k821212/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diacetyl-monoxime, Urea Nitrogen (CDW)
Date received	Apr 27, 1982
Decision date	Jul 22, 1982
Days to decision	86 days
Third-party review	No

**APPLICANT**

---

Company	<b>Omega Medical Electronics</b>
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1982-1983

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k821212/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026