

K881366 BIOTROL BUN ENZYMATIQUE UV H.P.May 16, 1988
46 days to decisionK881366 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k881366/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ) |
| Date received | Mar 31, 1988 |
| Decision date | May 16, 1988 |
| Days to decision | 46 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Biotrol, USA, Inc. |
| Location | Berwyn, PA, US |
| Contact | ALLAN C MURPHY |
| 510(k) history | 46 submissions · 46 cleared · 1987-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k881366/>; 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 June 30, 2026