

K800685 REAGENT FOR DETERM. CREATININE IN H/SERUMay 28, 1980
63 days to decisionK800685 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k800685/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Alkaline Picrate, Colorimetry, Creatinine (CGX) |
| Date received | Mar 26, 1980 |
| Decision date | May 28, 1980 |
| Days to decision | 63 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Solutions, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 26 submissions · 26 cleared · 1980-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k800685/> 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