

K813043 ULTRACHEM CREA ITEM #64972Nov 10, 1981
13 days to decisionK813043 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k813043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Oct 28, 1981
Decision date	Nov 10, 1981
Days to decision	13 days
Third-party review	No

APPLICANT

Company	Harleco
Location	Mchenry, IL, US
510(k) history	116 submissions · 116 cleared · 1976-1982

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k813043/> 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