

K040976 GENCHEM CREATININE REAGENTDec 27, 2004
257 days to decisionK040976 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k040976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Apr 14, 2004
Decision date	Dec 27, 2004
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genchem, Inc.
Location	Brea, CA, US
Contact	C.C. ALLAIN
510(k) history	8 submissions · 8 cleared · 2004-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040976/> 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 23, 2026