

K123586 EASYRA CREATININE REAGENTMay 15, 2013
175 days to decisionK123586 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k123586/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Nov 21, 2012
Decision date	May 15, 2013
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medica Corporation
Location	Bedford, MA, US
Contact	Photios Makris
510(k) history	7 submissions · 7 cleared · 2011-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123586/> 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 25, 2026