

**K061830 STAT PROFILE CRITICAL CARE XPRESS (CCX),
MODEL 1+**Nov 1, 2006
126 days to decisionK061830 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k061830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 28, 2006
Decision date	Nov 1, 2006
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nova Biomedical Corp.
Location	Mchenry, IL, US
Contact	PAUL W MACDONALD
510(k) history	89 submissions · 89 cleared · 1977-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061830/> 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 18, 2026