

**K080607 CALIBRATOR FOR AUTOMATED SYSTEMS (C.F.A.S.)
PROTEINS WITH MODEL 11355279160**May 12, 2008
69 days to decisionK080607 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k080607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Mar 4, 2008
Decision date	May 12, 2008
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	KATHIE J CUNNINGHAM
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080607/>; 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 9, 2026