

K760349 BILIRUBIN REF., SIGMA STOCK NO. 605-10Oct 5, 1976
64 days to decisionK760349 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k760349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Aug 2, 1976
Decision date	Oct 5, 1976
Days to decision	64 days
Third-party review	No

APPLICANT

Company	Sigma Chemical Co.
Location	Mchenry, IL, US
Website	https://www.sigmaaldrich.com
510(k) history	231 submissions · 231 cleared · 1976-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k760349/>; 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