

K964590 COLORMATE IIIJul 24, 1997
251 days to decisionK964590 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k964590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Nov 15, 1996
Decision date	Jul 24, 1997
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chromatics Color Sciences Intl., Inc.
Location	Rockville, MD, US
Contact	THOMMAS M TSAKERIS
510(k) history	2 submissions · 2 cleared · 1997-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964590/> 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 30, 2026