

K001687 COLORMATE TLC BILITEST SYSTEMSep 13, 2001
469 days to decisionK001687 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k001687/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Jun 1, 2000
Decision date	Sep 13, 2001
Days to decision	469 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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