

K093623 GEM PREMIER 4000 WITH IQM (ADDITION OF TOTAL BILIRUBIN PARAMETER), GEM CVP 2 (ADDITION OF TOTAL BILIRUBIM ASSIGNMENT TOJun 18, 2010
207 days to decisionK093623 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k093623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Nov 23, 2009
Decision date	Jun 18, 2010
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

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