

K040391 TOTAL BILIRUBIN REAGENT SETJun 2, 2004
106 days to decisionK040391 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k040391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Feb 17, 2004
Decision date	Jun 2, 2004
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pointe Scientific, Inc.,
Location	Mchenry, IL, US
Contact	RON JAMISON
510(k) history	74 submissions · 74 cleared · 1981-2007

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