

**K981609 BILIRUBIN-SL (DIRECT) ASSAY CATALOGUE
NUMBER 247-10,247-30**Jun 3, 1998
29 days to decisionK981609 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k981609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	May 5, 1998
Decision date	Jun 3, 1998
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Chemicals , Ltd.
Location	Charlottetown, P.E.I., CA
Contact	KAREN CALLBECK
510(k) history	66 submissions · 66 cleared · 1994-2007

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