

**K955880 DIRECT BILIRUBIN (DND) ASSAY, CATALOGUE
NUMBER 209-05**Aug 27, 1996
243 days to decisionK955880 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k955880/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received | Dec 28, 1995 |
| Decision date | Aug 27, 1996 |
| Days to decision | 243 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955880/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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