

**K973108 TOTAL PROTEIN (MICRO) ASSAY, CATALOGUE
NUMBER 450-50**Mar 2, 1998
195 days to decisionK973108 · Product code: **CEK** · Chemistry
Source: <https://www.510kdatabase.net/k973108/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Biuret (colorimetric), Total Protein (CEK) |
| Date received | Aug 19, 1997 |
| Decision date | Mar 2, 1998 |
| Days to decision | 195 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/k973108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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