

**K904660 ENZYMATIC BILIRUBIN (TOTAL), CATALOGUE NO.
202-14**Nov 20, 1990
36 days to decisionK904660 · Product code: **JFM** · Chemistry
Source: <https://www.510kdatabase.net/k904660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Oct 15, 1990
Decision date	Nov 20, 1990
Days to decision	36 days
Third-party review	No

APPLICANT

Company	Diagnostic Chemicals, Ltd. (Usa)
Location	Walker, MI, US
Contact	KAREN CALLBECK
510(k) history	77 submissions · 76 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904660/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026