

**K991866 BILIRUBIN, TOTAL AND DIRECT, PRODUCT NO,
122-01, 122-02, 122-03, 122-04**Aug 2, 1999
62 days to decisionK991866 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k991866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 1, 1999
Decision date	Aug 2, 1999
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	A.P. Total Care, Inc.
Location	Bridgeport, CT, US
Contact	LUIS P LEON
510(k) history	18 submissions · 18 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991866/> 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 30, 2026