

K955940 TOTAL BILIRUBIN REAGENTMar 13, 1996
83 days to decisionK955940 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k955940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Dec 21, 1995
Decision date	Mar 13, 1996
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Derma Media Lab., Inc.
Location	Santa Fe Springs, CA, US
Contact	CHARLES C ALLAIN
510(k) history	18 submissions · 18 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955940/> 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 July 1, 2026