

K897175 OLYMPUS DIRECT BILIRUBINMar 15, 1990
78 days to decisionK897175 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k897175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Dec 27, 1989
Decision date	Mar 15, 1990
Days to decision	78 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	ANNA G BENTLEY
510(k) history	288 submissions · 288 cleared · 1984-1994

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