

K821197 TOTAL BILIRUBIN REAGENT SETJul 13, 1982
77 days to decisionK821197 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k821197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Apr 27, 1982
Decision date	Jul 13, 1982
Days to decision	77 days
Third-party review	No

APPLICANT

Company	Omega Medical Electronics
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1982-1983

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Device record: <https://www.510kdatabase.net/k821197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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