

K771840 TOTAL BILIRUBINOct 19, 1977
28 days to decisionK771840 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k771840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Sep 21, 1977
Decision date	Oct 19, 1977
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Gamma Enterprises, Inc.
Location	Walker, MI, US
510(k) history	23 submissions · 23 cleared · 1977-1979

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Device record: <https://www.510kdatabase.net/k771840/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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