

K771089 UNIPAK TOTAL BILIRUBINJul 21, 1977
35 days to decisionK771089 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k771089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 16, 1977
Decision date	Jul 21, 1977
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Harleco
Location	Mchenry, IL, US
510(k) history	116 submissions · 116 cleared · 1976-1982

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Device record: <https://www.510kdatabase.net/k771089/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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