

K820675 BILIRUBIN(TOTAL) DETERMINATION CTMSApr 1, 1982
21 days to decisionK820675 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k820675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Mar 11, 1982
Decision date	Apr 1, 1982
Days to decision	21 days
Third-party review	No

APPLICANT

Company	The Dow Chemical Co.
Location	Walker, MI, US
Website	https://www.dow.com
510(k) history	26 submissions · 26 cleared · 1976-1982

The Dow Chemical Co. is an American multinational chemical corporation headquartered in Midland, Michigan. The company operates globally with presence in approximately 160 countries and employs about 36,000 people worldwide. The Dow Chemical Co. has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company specialized in Chemistry devices, which represented 92% of its regulatory submissions. Clearances span from 1976 to 1982, establishing a historical record in clinical laboratory diagnostics and analytical instrumentation. T...

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