

**K770458 BILIRUBIN PROCEDURE, TEKPOINT TOT & DIR.**May 10, 1977  
63 days to decisionK770458 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k770458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Mar 8, 1977
Decision date	May 10, 1977
Days to decision	63 days
Third-party review	No

**APPLICANT**

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Company	<b>Icn Pharmaceuticals, Inc.</b>
Location	Walker, MI, US
510(k) history	30 submissions · 30 cleared · 1977-2002

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k770458/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026