

**K855079 NEONATAL BILIRUBIN(NBIL) TEST PACK 67661/95**Mar 5, 1986  
76 days to decisionK855079 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k855079/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Dec 19, 1985
Decision date	Mar 5, 1986
Days to decision	76 days
Third-party review	No

**APPLICANT**

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Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k855079/>; 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 14, 2026