

K931888 TOTAL BILIRUBINJul 27, 1993
103 days to decisionK931888 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k931888/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received | Apr 15, 1993 |
| Decision date | Jul 27, 1993 |
| Days to decision | 103 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Em Diagnostic Systems, Inc. |
| Location | Walker, MI, US |
| Contact | CAROL FAULKNER |
| 510(k) history | 288 submissions · 288 cleared · 1984-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k931888/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026