

**K964913 IRON REAGENT**Feb 20, 1997  
73 days to decisionK964913 · Product code: **J1Y** · Chemistry  
Source: <https://www.510kdatabase.net/k964913/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Photometric Method, Iron (non-heme) (J1Y) |
| Date received         | Dec 9, 1996                               |
| Decision date         | Feb 20, 1997                              |
| Days to decision      | 73 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Derma Media Lab., Inc.</b>           |
| Location       | Santa Fe Springs, CA, US                |
| Contact        | CHARLES C ALLAIN, PH.D.                 |
| 510(k) history | 18 submissions · 18 cleared · 1996-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964913/> 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 July 1, 2026