

**K944911 ACE IRON REAGENT**Feb 10, 1995  
128 days to decisionK944911 · Product code: **J1Y** · Chemistry  
Source: <https://www.510kdatabase.net/k944911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photometric Method, Iron (non-heme) (J1Y)
Date received	Oct 5, 1994
Decision date	Feb 10, 1995
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Schiapparelli Biosystems, Inc.</b>
Location	Fairfield, NJ, US
Contact	MARK A SPAIN
510(k) history	24 submissions · 24 cleared · 1993-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944911/> 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 June 28, 2026