

K895249 SYSTEMATE(TM) IRON ITEM NUMBER: 65417Oct 31, 1989
71 days to decisionK895249 · Product code: JIY · Chemistry
Source: <https://www.510kdatabase.net/k895249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photometric Method, Iron (non-heme) (JIY)
Date received	Aug 21, 1989
Decision date	Oct 31, 1989
Days to decision	71 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895249/>; 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