

K963498 FERR FLEX REAGENT CARTRIDGEJan 24, 1997
143 days to decisionK963498 · Product code: **JMG** · Chemistry
Source: <https://www.510kdatabase.net/k963498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay (two-site Solid Phase), Ferritin (JMG)
Date received	Sep 3, 1996
Decision date	Jan 24, 1997
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Chemistry Systems, Inc.
Location	Newark, DE, US
Contact	CATHY P CRAFT
510(k) history	13 submissions · 13 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963498/> 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 June 30, 2026