

K834396 DIRECT IRON REAGENT SETFeb 21, 1984
69 days to decisionK834396 · Product code: **CFM** · Chemistry
Source: <https://www.510kdatabase.net/k834396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bathophenanthroline, Colorimetry, Iron (non-heme) (CFM)
Date received	Dec 14, 1983
Decision date	Feb 21, 1984
Days to decision	69 days
Third-party review	No

APPLICANT

Company	Seragen Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1982-1987

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k834396/> 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 29, 2026