

K992157 CHIRON DIAGNOSTICS ACS: 180 FERRITIN ASSAYAug 5, 1999
41 days to decisionK992157 · Product code: **DBF** · Immunology
Source: <https://www.510kdatabase.net/k992157/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ferritin, Antigen, Antiserum, Control (DBF) |
| Date received | Jun 25, 1999 |
| Decision date | Aug 5, 1999 |
| Days to decision | 41 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Chiron Diagnostics Corp. |
| Location | Medfield, MA, US |
| Contact | William J Pignato |
| 510(k) history | 20 submissions · 20 cleared · 1997-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992157/> 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 28, 2026