

**K970612 SEALITE SCIENCES, INC. AQUALITE FERRITIN
ASSAY**Jun 24, 1997
126 days to decisionK970612 · Product code: **DBF** · Immunology
Source: <https://www.510kdatabase.net/k970612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferritin, Antigen, Antiserum, Control (DBF)
Date received	Feb 18, 1997
Decision date	Jun 24, 1997
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sealite Sciences, Inc.
Location	Bogart, GA, US
Contact	CATHRYN N CAMBRIA
510(k) history	11 submissions · 11 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970612/>; 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