

K820643 ORTHO SPECTRUM III & ORTHO-MUNE OKJul 14, 1982
128 days to decisionK820643 · Product code: **LIZ** · Hematology
Source: <https://www.510kdatabase.net/k820643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, T Lymphocyte Surface Marker (LIZ)
Date received	Mar 8, 1982
Decision date	Jul 14, 1982
Days to decision	128 days
Third-party review	No

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k820643/> 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