

K823490 ORTHO BI-LEVEL ASSAYED LIPID PROFILEJan 5, 1983
43 days to decisionK823490 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k823490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Nov 23, 1982
Decision date	Jan 5, 1983
Days to decision	43 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.net

Device record: <https://www.510kdatabase.net/k823490/> 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