

K813167 ORTHO UNASSAYED CONTROL SERUM LEVEL IINov 24, 1981
12 days to decisionK813167 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k813167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Nov 12, 1981
Decision date	Nov 24, 1981
Days to decision	12 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k813167/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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