

K821026 BI-LEVEL ASSAYED TUMOR MARKER & ANTINAug 10, 1982
119 days to decisionK821026 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k821026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Apr 13, 1982
Decision date	Aug 10, 1982
Days to decision	119 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/k821026/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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