

K831670 ORTHO*PAP-IA ENDOGENOUS ENZYME IMMUNOAug 24, 1983
93 days to decisionK831670 · Product code: **JFH** · Chemistry
Source: <https://www.510kdatabase.net/k831670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid Phosphatase (prostatic), Tartrate Inhibited (JFH)
Date received	May 23, 1983
Decision date	Aug 24, 1983
Days to decision	93 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/k831670/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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