

K811757 NEIA PAP ENZYMEIMMUNOASSAYAug 13, 1981
52 days to decisionK811757 · Product code: **JFH** · Immunology
Source: <https://www.510kdatabase.net/k811757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid Phosphatase (prostatic), Tartrate Inhibited (JFH)
Date received	Jun 22, 1981
Decision date	Aug 13, 1981
Days to decision	52 days
Third-party review	No

APPLICANT

Company	New England Immunology Assoc.
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1978-1981

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Device record: <https://www.510kdatabase.net/k811757/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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