

**K864945 TANDEM(R) M-PAK(TM) PAP IMMUNOENZYMETRIC ASSAY**Jan 5, 1987  
19 days to decisionK864945 · Product code: JFH · Chemistry  
Source: <https://www.510kdatabase.net/k864945/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid Phosphatase (prostatic), Tartrate Inhibited (JFH)
Date received	Dec 17, 1986
Decision date	Jan 5, 1987
Days to decision	19 days
Third-party review	No

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
Contact	BRUNI, PH.D.
510(k) history	63 submissions · 63 cleared · 1981-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864945/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026