FDA 510(k) Premarket Notification

K981573 UBI MAGIWEL PAP (PROSTATIC ACID PHOSPHATASE) EIA QUANTITATVE

CLEARED

Sep 15, 1998
134 days to decision

K981573 · Product code: **JFH** · Chemistry
Source: https://www.510kdatabase.net/k981573/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid Phosphatase (prostatic), Tartrate Inhibited (JFH)
Date received	May 4, 1998
Decision date	Sep 15, 1998
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**United Biotech, Inc.**
Location	Mountain View, CA, US
Contact	SHARON SUN
510(k) history	22 submissions · 22 cleared · 1985-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k981573/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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