

**K012943 THE QUANTECH FASTRAQ AUTOMATED ANALYZER,
AND THE QUANTECH PREPAQ TOTAL HCG TEST CARTRIDGE**

Jan 18, 2002
140 days to decision

K012943 · Product code: **NAL** · Chemistry
Source: <https://www.510kdatabase.net/k012943/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Immunoassay, Biosensor, Hcg (NAL)
Date received	Aug 31, 2001
Decision date	Jan 18, 2002
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quantech , Ltd.
Location	Northridge, CA, US
Contact	ROBIN J HELLEN
510(k) history	3 submissions · 3 cleared · 1999-2002

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k012943/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026