

K181945 QuickScreen Pro Multi Drug Screening Test, Model 9395ZOct 18, 2018
90 days to decisionK181945 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k181945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jul 20, 2018
Decision date	Oct 18, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phamatech, Inc.
Location	San Diego, CA, US
Contact	Robert Merlock
510(k) history	15 submissions · 15 cleared · 2001-2018

REGULATORY CONSULTANT

Consulting firm	KARA & Associates
Contact	Korina A. Akhondzadeh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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