

K183530 TruDiagnosis SystemMay 24, 2019
156 days to decisionK183530 · Product code: **ODW** · Toxicology
Source: <https://www.510kdatabase.net/k183530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytochrome P450 2c9 (cyp450 2c9) Drug Metabolizing Enzyme Genotyping System (ODW)
Date received	Dec 19, 2018
Decision date	May 24, 2019
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Akonn Biosystems, Inc.
Location	Frederick, MD, US
Contact	Charles Daitch
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	MethodSense, Inc.
Contact	Rita King

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

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