

**K140546 HEALGEN THC ONE STEP MARIJUANA TEST ,
HEALGEN MAMP ONE STEP METHAMPHETAMINE TEST**Jun 6, 2014
94 days to decisionK140546 · Product code: **LDJ** · Chemistry
Source: <https://www.510kdatabase.net/k140546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Mar 4, 2014
Decision date	Jun 6, 2014
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Healgen Scientific, LLC
Location	Houston, TX, US
Contact	Joe Shia
Website	https://www.healgen.com
510(k) history	27 submissions · 27 cleared · 2012-2026

Healgen Scientific, LLC is a leading in-vitro diagnostics (IVD) developer and manufacturer based in Houston, Texas. Established in 2007, the company specializes in high-quality diagnostic testing technologies across multiple therapeutic areas. Healgen has achieved FDA 510(k) clearances from total submissions since 2012, with no denied submissions on record. The company's regulatory portfolio is dominated by toxicology devices, including drug screening and fentanyl detection products, alongside offerings in chemistry, microbiology, and infectious disease diagnostics. The I...

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