

**K153597 Healgen Multi-Drug Urine Test Cup, Healgen Multi-Drug Urine Test Dip Card**May 23, 2016  
159 days to decisionK153597 · Product code: **JXM** · Toxicology  
Source: <https://www.510kdatabase.net/k153597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Dec 16, 2015
Decision date	May 23, 2016
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healgen Scientific, LLC</b>
Location	Houston, TX, US
Contact	Jianqiu Fang
Website	<a href="https://www.healgen.com">https://www.healgen.com</a>
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 l...

**REGULATORY CONSULTANT**

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Consulting firm	<b>LSI International, Inc.</b>
Contact	JOE XIA

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k153597/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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