

**K151642 Heagen Multi-Drug Urine Test Cup, Healgen Multi-Drug Urine Test Dip Card**Aug 13, 2015  
56 days to decisionK151642 · Product code: **JXM** · Chemistry  
Source: <https://www.510kdatabase.net/k151642/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Jun 18, 2015
Decision date	Aug 13, 2015
Days to decision	56 days
Third-party review	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 I...