

K150356 Healgen Multi-Drug Urine Test Cup, Healgen Multi-Drug Urine Test Dip CardMay 13, 2015
90 days to decisionK150356 · Product code: **JXM** · Chemistry
Source: <https://www.510kdatabase.net/k150356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Feb 12, 2015
Decision date	May 13, 2015
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Healgen Scientific, LLC
Location	Houston, TX, US
Contact	JIANQIU FANG
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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