

K143187 Healgen Amphetamine Test (Strip, Cassette, Cup, Dip Card), Healgen Oxycodone Test (Strip, Cassette, Cup, Dip Card)Jan 27, 2015
83 days to decisionK143187 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k143187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Nov 5, 2014
Decision date	Jan 27, 2015
Days to decision	83 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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