

**K142280 Healgen Oxazepam Test (Strip, Cassette, Cup, Dip Card), Healgen Morphine Test (Strip, Cassette, Cup, Dip Card)**Oct 16, 2014  
62 days to decisionK142280 · Product code: **DJG** · Chemistry  
Source: <https://www.510kdatabase.net/k142280/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 15, 2014
Decision date	Oct 16, 2014
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142280/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 6, 2026