

**K141647 HEALGEN COC ONE STEP COCAINE TEST  
STRIP:MORHPINE TEST STRIP (CASSETTE, CUP, DIP CARD)**Jul 17, 2014  
28 days to decisionK141647 · Product code: **DIO** · Chemistry  
Source: <https://www.510kdatabase.net/k141647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 19, 2014
Decision date	Jul 17, 2014
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healgen Scientific, LLC</b>
Location	Houston, TX, US
Contact	Joe Shia
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...

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