

K151348 Healgen Propoxyphene Test (Strip, Cassette, Cup, Dip Card), Healgen Nortriptyline Test (Strip, Cassette, Cup, Dip Card), Healgen EDDP (Methadone Metabolite) Test (Strip, Cassette, Cup, Dip Card)

Aug 18, 2015
90 days to decision

K151348 · Product code: **LFG** · Toxicology
Source: <https://www.510kdatabase.net/k151348/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Tricyclic Antidepressant Drugs (LFG)
Date received	May 20, 2015
Decision date	Aug 18, 2015
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	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...

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	JOE XIA

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
