

**K151046 illumigene HSV 1&2 DNA Amplification Assay,
illumigene HSV 1&2 External Control Kit, illumipro-10**Jul 17, 2015
88 days to decisionK151046 · Product code: **PGI** · Microbiology
Source: <https://www.510kdatabase.net/k151046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Virus (vzv, Hsv1, Hsv2), Dna Detection Assay For Cutaneous And Mucocutaneous Lesion Samples (PGI)
Date received	Apr 20, 2015
Decision date	Jul 17, 2015
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Bioscience, Inc.
Location	Cincinnati, OH, US
Contact	STEFANIE JOHNS
Website	https://www.meridianbioscience.com
510(k) history	38 submissions · 37 cleared · 2003-2025

Meridian Bioscience, Inc. is a diagnostic and life science solutions company with a manufacturing facility in Cincinnati, US. The company develops integrated diagnostic products and molecular reagents for clinical and research applications. Meridian has received FDA 510(k) clearances from total submissions since 2003. The company specializes exclusively in Microbiology devices, including molecular detection assays, pathogen identification systems, and diagnostic analyzers. The latest clearance in 2025 reflects continued regulatory activity and product innovation. Recent c...

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Device record: <https://www.510kdatabase.net/k151046/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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