

**K122019 STREPTOCOCCUS APP. SEROLOGICAL REAGENTS**Sep 13, 2012  
65 days to decisionK122019 · Product code: **OYZ** · Microbiology  
Source: <https://www.510kdatabase.net/k122019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Group A Streptococcus Nucleic Acid Amplification Assay System (OYZ)
Date received	Jul 10, 2012
Decision date	Sep 13, 2012
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meridian Bioscience, Inc.</b>
Location	Cincinnati, OH, US
Contact	Michelle L Smith
Website	<a href="https://www.meridianbioscience.com">https://www.meridianbioscience.com</a>
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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