K112125 ILLUMIGENE GROUP B STREPTOCOCCUS ,EXTERNAL CONTROL KIT

CLEARED

Dec 5, 2011
133 days to decision

K112125 · Product code: **NJR** · Microbiology
Source: https://www.510kdatabase.net/k112125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen Test (NJR)
Date received	Jul 25, 2011
Decision date	Dec 5, 2011
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	SUSAN D ROLIH
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...