FDA 510(k) Premarket Notification

K162772 ARIES GBS Assay

CLEARED

Dec 23, 2016
81 days to decision

K162772 · Product code: **NJR** · Microbiology
Source: https://www.510kdatabase.net/k162772/

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	Oct 3, 2016
Decision date	Dec 23, 2016
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Luminex Corporation**
Location	Austin, TX, US
Contact	CHRISTIE HUGHES
Website	http://www.luminexcorp.com/
510(k) history	14 submissions · 14 cleared · 2015-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162772/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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