FDA 510(k) Premarket Notification

CLEARED

K171441 ARIES C. difficile Assay Complete Kit, ARIES C. difficile Assay Protocol File Kit, ARIES C. difficile Assay Kit (24 cassettes), ARIES Stool Resuspension Kit

Jul 21, 2017
66 days to decision

K171441 · Product code: **OZN** · Microbiology
Source: https://www.510kdatabase.net/k171441/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	May 16, 2017
Decision date	Jul 21, 2017
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Luminex Corporation**
Location	Austin, TX, US
Contact	Wendy Ricker
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/k171441/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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