FDA 510(k) Premarket Notification

K160517 ARIES System

CLEARED

Apr 12, 2016
48 days to decision

K160517 · Product code: **OOI** · Microbiology
Source: https://www.510kdatabase.net/k160517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Feb 24, 2016
Decision date	Apr 12, 2016
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

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/k160517/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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