

**K211815 LifeScale Gram Negative Kit (LSGN) with the LifeScale AST System**Apr 2, 2024  
1026 days to decisionK211815 · Product code: **SAN** · Microbiology  
Source: <https://www.510kdatabase.net/k211815/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	Jun 11, 2021
Decision date	Apr 2, 2024
Days to decision	1026 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Affinity Biosensors</b>
Location	Santa Barbara, CA, US
Contact	Ken Babcock
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211815/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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