

K193490 SensiTox C. difficile Toxin TestJul 8, 2021
569 days to decisionK193490 · Product code: **LLH** · Microbiology
Source: <https://www.510kdatabase.net/k193490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Dec 17, 2019
Decision date	Jul 8, 2021
Days to decision	569 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	First Light Diagnostics, Inc.
Location	Chelmsford, MA, US
Contact	Joanne Spadaro
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	MDC Associates, LLC
Contact	Fran White

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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