FDA 510(k) Premarket Notification

K193490 SensiTox C. difficile Toxin Test

CLEARED

Jul 8, 2021
569 days to decision

K193490 · 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 Spadoro
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