

K232545 The SensiTox B. anthracis Toxin TestNov 20, 2023
90 days to decisionK232545 · Product code: **QUU** · Microbiology
Source: <https://www.510kdatabase.net/k232545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Simple In Vitro Diagnostic Device For The Detection Of Secreted Proteins From Bacillus Spp. In Human Clinical Samples (QUU)
Date received	Aug 22, 2023
Decision date	Nov 20, 2023
Days to decision	90 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

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