FDA 510(k) Premarket Notification

CLEARED

K233410 LIAISON PLEX Respiratory Flex Assay

Mar 1, 2024
147 days to decision

K233410 · Product code: **QOF** · Microbiology
Source: https://www.510kdatabase.net/k233410/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Oct 6, 2023
Decision date	Mar 1, 2024
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Luminex Corporation**
Location	Austin, TX, US
Contact	Tara Viviani
Website	http://www.luminexcorp.com/
510(k) history	14 submissions · 14 cleared · 2015-2025