

K233655 Lingo Glucose System

May 29, 2024
197 days to decisionK233655 · Product code: **SAF** · Chemistry
Source: <https://www.510kdatabase.net/k233655/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitor For Non-intensive Glucose Monitoring, Over-the-counter (SAF)
Date received	Nov 14, 2023
Decision date	May 29, 2024
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott
Location	St. Paul, MN, US
Contact	Juni Sarkar
Website	http://www.abbott.com
510(k) history	12 submissions · 12 cleared · 2018-2026

Abbott is a global healthcare company developing life-changing medical devices and solutions. The company operates with a manufacturing facility in St. Paul, Minnesota. Abbott serves patients across multiple therapeutic areas including diabetes care, nutrition, diagnostics, and cardiovascular health. Abbott has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centers on Cardiovascular devices, which represent 91% of its FDA 510(k) portfolio. Abbott's first clearance was granted in 2018, with the mo...

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Device record: <https://www.510kdatabase.net/k233655/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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