

K221326 Nova Allegro HbA1c Assay, Nova Allegro AnalyzerNov 22, 2024
931 days to decisionK221326 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k221326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 6, 2022
Decision date	Nov 22, 2024
Days to decision	931 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nova Biomedical Corporation
Location	Waltham, MA, US
Contact	Cesidio Tempesta
510(k) history	40 submissions · 40 cleared · 2011-2026

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