

K221924 Digital RoutinesMar 15, 2023
257 days to decisionK221924 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k221924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Jul 1, 2022
Decision date	Mar 15, 2023
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gnc Holdings, LLC
Location	Pittsburgh, PA, US
Contact	YongKai Wong
Website	http://www.gnc.com
510(k) history	1 submissions · 1 cleared · 2023-2023

Gnc Holdings, LLC is a medical device company with a manufacturing facility in Pittsburgh, US. The company specializes in Chemistry devices for clinical and laboratory applications. The company has received FDA 510(k) clearance from total submission. Gnc Holdings, LLC focused exclusively on Chemistry devices, with its clearance granted in 2023. The company is currently inactive and represents a historical regulatory record. Explore the device names, product codes, and clearance dates in the database to review the company's regulatory history.