March 15, 2023

GNC Holdings, LLC
Yongkai Wong
Executive Vice Chairman
75 Hopper Pl
Pittsburgh, PA 15222

Re: K221924
Trade/Device Name: Digital Routines
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: NDC
Dated: December 14, 2022
Received: December 15, 2022

Dear Yongkai Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.03.15 16:39:05 -04'00'

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221924

Device Name
Digital Routines

Indications for Use *(Describe)*
Digital Routines is indicated for use by healthcare providers (HCPs) and their patients - aged 21 years and older - who have type 2 diabetes. Digital Routines is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The Digital Routines system analyzes and reports blood glucose test results and supports medication adherence. In addition, Digital Routines provides coaching messages (motivational, behavioral, and educational) based on blood glucose values and trends. It includes software intended for use on mobile phones (for patients) or personal computers (for HCPs) in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information. The following Digital Routines insulin management features are for prescription use only:

• For bolus insulin users with type 2 diabetes, Digital Routines includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or blood glucose value. The healthcare provider must activate the insulin dose calculator for patient.

• For basal insulin users with type 2 diabetes, Digital Routines includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a healthcare provider knowledgeable in the care and management of diabetes. The healthcare provider must activate the IAP and configure it with patient-specific parameters.

Digital Routines is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Number: K221924

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant Information:

Date Prepared: March 13, 2023

Name: GNC Holdings, LLC
Address: 75 Hopper Pl
Pittsburgh PA, 15222

Contact Person: YongKai Wong
Executive Vice Chairman
yongkaiwong@citiccapital.com
Phone: 412-219-3879

Device Information:

Trade Name: Digital Routines
Common Names: Personal Diabetes Management System

Product Code (s): NDC

Regulation(s): 21 CFR 868.1890 - Predictive pulmonary-function value calculator
Classification: Class II

Predicate Device:

- WellDoc Inc. – BlueStar® Rx (K203434)

Device Description:

The Digital Routines is a stand-alone medical software system intended to be used by patients aged 21 and older who have type 2 diabetes. Digital Routines is a new kind of approach to support in helping patients manage their type 2 diabetes. Digital Routines real-time feedback and guidance fit into daily life to help patients stay on track with their diabetes care plan.

Digital Routines is accessible directly from the patient's mobile phone, but also includes the patient's HCP throughout the process. It supports the healthcare provider`s treatment plan while helping with building the patient's knowledge about diabetes and stay motivated. The device also incorporates an insulin calculator for bolus insulin users and an insulin adjustment program for basal insulin users. These features require the approval of a physician before the patient can access them.

The system comprises three core software components:

(i) the Patient Mobile Application
(ii) the HCP Web Portal
(iii) the Enterprise Director Web Portal

HCPs can authorize the Insulin Calculator or initiate an Insulin Adjustment Program (Rx only). The Insulin Adjustment Program is designed to help physicians and their patients with type 2 diabetes to adjust their long-acting (basal) insulin to improve diabetes management. The program works by collecting and analyzing blood glucose readings to adjust basal insulin doses according to the physician's instructions. Physicians can view and adjust their patient's treatment plan at any time, and they receive safety notifications such as if a patient experiences hypoglycemia or takes insulin doses that substantially differ from the recommended amount.

The Insulin Calculator uses the physician authorized regimen to calculate the corresponding dose of bolus insulin to take based on a patient's carbs and blood glucose value. Patients eligible to use the Insulin Calculator have the option within Digital Routines to request access to it. The patient's physician must authorize the Insulin Calculator for it to be activated. Prior to using the Insulin Calculator, the patient will be required to complete in-app training on the use of the calculator. The Insulin Calculator may also include an optional Insulin on Board feature that must be authorized by the physician.

Indications for Use:

Digital Routines is indicated for use by healthcare providers (HCPs) and their patients – aged 21 years and older - who have type 2 diabetes. Digital Routines is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The Digital Routines system analyzes and reports blood glucose test results and supports medication adherence. In addition, Digital Routines provides coaching messages (motivational, behavioral, and educational) based on blood glucose values and trends. It includes software intended for use on mobile phones (for patients) or personal computers (for HCPs) in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The following Digital Routines insulin management features are for prescription use only:

• For bolus insulin users with type 2 diabetes, Digital Routines includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or blood glucose value. The healthcare provider must activate the insulin dose calculator for patient.

• For basal insulin users with type 2 diabetes, Digital Routines includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin

doses for titrating insulin levels based on configuration by a healthcare provider knowledgeable in the care and management of diabetes. The healthcare provider must activate the IAP and configure it with patient-specific parameters.

Digital Routines is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Summary Comparison to Predicate:

The following tables provide a summary of substantial equivalence between the subject device and the cited predicate. The subject device has the same intended use and substantially equivalent characteristics that do not raise different questions of safety or effectiveness.

Comparison to Predicate Device:
The following table provides a comparison of the detection features of the Digital Routines device and the predicate device:

Features	GNC Holdings, LLC Digital Routines	WellDoc Inc. BlueStar Rx (K203434)	Comparison
General Characteristics			
Classification	21 CFR 868.1890	21 CFR 868.1890	Equivalent
Product Code	NDC	NDC	Equivalent
Class	II	II	Equivalent
Indications for Use	Digital Routines is indicated for use by healthcare providers (HCPs) and their patients – aged 21 years and older - who have type 2 diabetes. Digital Routines is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The Digital Routines system	BlueStar® Rx is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. The BlueStar® Rx is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The	Equivalent

Features	GNC Holdings, LLC Digital Routines	WellDoc Inc. BlueStar Rx (K203434)	Comparison
	analyzes and reports blood glucose test results and supports medication adherence. In addition, Digital Routines provides coaching messages (motivational, behavioral, and educational) based on blood glucose values and trends. It includes software intended for use on mobile phones (for patients) or personal computers (for HCPs) in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.	BlueStar® Rx analyzes and reports blood glucose test results and supports medication adherence. In addition, the BlueStar® Rx provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.	
Environment of Use	Home	Home	Equivalent
Target Population	Patients with Type 2 diabetes; Aged 21 years and older	Patients with Type 1 or Type 2 diabetes; Aged 18 years and older	Equivalent – the predicate device is also indicated for patients with Type 1 diabetes, however, both devices are indicated for patients with Type 2 diabetes.
Technological Characteristics			
Software	Yes	Yes	Equivalent - both devices contain software. Differences in the specific software implementation do not raise different questions of safety and

Features	GNC Holdings, LLC Digital Routines	WellDoc Inc. BlueStar Rx (K203434)	Comparison
			effectiveness.
HCP Portal	Yes	Yes	Equivalent – both devices provide a web portal for HCP users
Patient App	Mobile application	Mobile application, web portal	Equivalent – both devices include a mobile application for patients. The predicate device also includes a web portal. This difference does not raise different questions of safety and effectiveness as the web portal's functionality is largely replicated in the mobile application.
Logbook	Supports BG, carbs, activities, weight, waistline, blood pressure, sleep information,	Supports BG, carbs, activities	Equivalent – the subject device allows for the logging of additional health parameters. This difference does not raise different questions of safety and effectiveness.
Ability to Log Medications	Yes	Yes	Equivalent
Supported Mobile Platforms	Android, iOS	Android, iOS	Equivalent
Support for Bluetooth glucose meters	Yes	Yes	Equivalent – both devices support specific Bluetooth connected glucose meters

Features	GNC Holdings, LLC Digital Routines	WellDoc Inc. BlueStar Rx (K203434)	Comparison
Insulin Dose Calculator	Insulin Calculator for bolus insulin users Insulin Adjustment Program for basal insulin users	Bolus Insulin Calculation Pre-mixed Insulin Calculation Basal (long-acting) Insulin Titration	Equivalent – both devices support insulin dose calculation and dose adjustment for bolus and basal insulin users respectively.
Support for Insulin on Board	Yes (Rx only)	Yes (Rx only)	Equivalent – both devices incorporate the Insulin on Board in calculation of the recommended dose.

Summary of Performance Testing

Software V&V testing was performed on the device to ensure that the device meets all applicable software requirements. The cybersecurity of the device was evaluated in accordance with the FDA guidance documents on cybersecurity. Human factors testing was conducted to validate the device for use according to its labeling. The device has passed all testing.

Software

The software in the device is a Major level of concern. Software V&V testing has demonstrated that the device meets the applicable software requirements.

Conclusion

Based upon the intended use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Digital Routines has been shown to be substantially equivalent to the legally-marketed predicate.