510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I   Background Information:

A   510(k) Number

K221924

B   Applicant

GNC Holdings, LLC

C   Proprietary and Established Names

Digital Routines

D   Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive pulmonary-function value calculator	Clinical Chemistry

II   Submission/Device Overview:

A   Purpose for Submission:

New device

B   Type of Test:

Insulin dose (basal and bolus) calculation and titration.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Contraindications:

Digital Routines is not indicated for people with the following conditions:
1. Age < 21
2. Pregnant or breastfeeding
3. The types of diabetes other than Type 2 Diabetes (such as type 1 diabetes, gestational diabetes etc.)
4. Diagnosed with severe cardiovascular disease, severe liver disease, severe kidney disease, cancer or blood cancer, autoimmune disease, proliferative retinopathy, glaucoma or other severe eye diseases, other severe diseases
5. People who have ever lost consciousness due to low blood glucose or had more than two hypoglycemic incidents in last week (blood glucose below 70 mg/dL)
6. People whose most recent systolic blood pressure ≥ 180/110 mmHg
7. People who are using insulin pumps

For patients who will use the Insulin Adjustment Program-Basal Insulin section:
1. Age < 21
2. BMI < 18.5kg/m^2
3. Type 1 diabetes, Gestational Diabetes Mellitus, or Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes; drug (glucocorticoid) or chemical induced diabetes, pancreatic diabetes or diabetes in the context of disease of the exocrine pancreas
4. A history of acute diabetic complications (Diabetic Ketoacidosis or Nonketotic Hyperosmolar Coma) in the last month
5. Frequent hypoglycemia (more than twice in the last week)
6. Woman who is pregnant, breastfeeding, or trying to get pregnant
7. Hepatic failure, kidney failure, or heart failure
8. Be allergic to insulin or any component of insulin injection

For patients who will use the Insulin Calculator-Bolus Insulin section:
1. Age < 21
2. BMI < 18.5kg/m^2
3. Type 1 diabetes, Gestational Diabetes Mellitus, or Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes; drug (glucocorticoid) or chemical induced diabetes, pancreatic diabetes or diabetes in the context of disease of the exocrine pancreas
4. A history of acute diabetic complications (Diabetic Ketoacidosis or Nonketotic Hyperosmolar Coma) in the last month
5. Frequent hypoglycemia (more than twice in the last week)
6. Ever lost consciousness because of hypoglycemia (a history of level 3 hypoglycemia)
7. Woman who is pregnant, breastfeeding, or trying to get pregnant
8. Hepatic failure, kidney failure, or heart failure
9. Be allergic to insulin or any component of insulin injection

D Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Digital Routines is designed to work with glucose results reported in mg/dL and cannot be safely used with mmol/L values. To avoid harm please ensure that any glucose meter used with Digital Routines is set for blood glucose values in mg/dL.

IV   Device/System Characteristics:

A 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 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 to incorporate 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 is comprised of 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 IAP can be used for up to 90 days or until fasting blood glucose measurements are within the target range, whichever is sooner. The program works by collecting and analyzing blood glucose readings to adjust basal insulin doses according to the physician's instructions. The Insulin Adjustment Program supports "long-acting" insulins such as Basaglar, Lantus, Toujeo (Insulin Glargine), Levemir (Insulin Detemir) or Tresiba (Insulin Degludec). 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 supports "fast-acting" insulins such as Novolog or Fiasp (insulin aspart), Humalog or Admelog (insulin lispro), Lyumjev (insulin lispro – aabc) andquick Apidra (insulin glulisine). The Insulin Calculator may also include an optional Insulin on Board feature that must be authorized by the physician.

B   **Instrument Description Information:**

1. <u>Instrument Name:</u>

   Digital Routines

2. <u>Specimen Identification:</u>

   Not Applicable.

3. <u>Specimen Sampling and Handling</u>:

   Not Applicable.

4. <u>Calibration</u>:

   Not Applicable.

5. Can Quality Control:

   Not Applicable.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V   Substantial Equivalence Information:

A Predicate Device Name(s):

BlueStar Rx

B Predicate 510(k) Number(s):

K203434

C Comparison with Predicate(s):

Device & Predicate Device(s):	K221924	K203434
Device Trade Name	Digital Routines	BlueStar Rx
General Device Characteristic Similarities		
Intended Use/Indications For Use	Determination of insulin dose based on user entered data	Same
Environment of Use	Home	Same
User Interface	Mobile app and HCP portal	Same
General Device Characteristic Differences		
Type of Insulin (long-acting)	Basaglar U-100 Lantus U-100 Toujeo U-300 Levemir U-100 Tresiba U-100 Tresiba U-200	Basaglar U-100 Lantus U-100 Levemir U-100 Tresiba U-100 Tresiba U-200 Toujeo U-300 Xultophy 100/3.6 Soliqua 100/33

	Novolog U-100 Fiasp U-100 Humalog U-100 Humalog U-200 Admelog U-100 Lyumjev U-100 Lyumjev U-200 Apidra U-100	Admelog U-100 Apidra U-100 Fiasp U-100 Humalog U-100 Humalog U-200 Novolog U-100
Type of Insulin (fast-acting)		
Type of Insulin Dose Calculator	Bolus Insulin Calculator Basal Insulin Titration	Bolus Insulin Calculator Pre-mixed Insulin Calculator Basal Insulin Titration

VI   Standards/Guidance Documents Referenced:

ANSI AAMI IEC 62304:2006/A1:2016
Medical device software - Software life cycle processes

ANSI AAMI IEC 62366-1:2015+AMD1:2020
Medical devices Part 1: Application of usability engineering to medical devices

ANSI AAMI ISO 14971: 2019
Medical devices - Applications of risk management to medical devices

ISO 20417 First edition 2021-04 Corrected version 2021-12
Medical devices - Information to be supplied by the manufacturer

VII   Performance Characteristics (if/when applicable):

A   Analytical Performance:

1. <u>Precision/Reproducibility:</u>

   Not Applicable.

2. <u>Linearity:</u>

   Not Applicable.

3. <u>Analytical Specificity/Interference:</u>

   Not Applicable.

4. <u>Accuracy (Instrument):</u>

   Not Applicable.

5. <u>Carry-Over:</u>

   Not Applicable.

B Other Supportive Instrument Performance Characteristics Data:

<u>Usability:</u>
The sponsor provided protocols and results from human factors studies to demonstrate that users can perform all critical tasks associated with the new device features. Subjects were representative of the device's intended use population, including patients over 21 years of age and healthcare providers. The results of these studies were adequate to demonstrate safe use of the device and support substantial equivalence to the predicate.

<u>Software:</u>
The firm provided software documentation consistent with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005), and consistent with software with a major level of concern. Software documentation was acceptable.

VIII   Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX   Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.