



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

HMD BIOMEDICAL, INC.  
AXEL LIN  
QUALITY ASSURANCE MANAGER  
NO 181 MINSHENG ST, XINPU TOWNSHIP  
HSINCHU 305, TAIWAN

May 14, 2015

Re: K140150

Trade/Device Name: Goodlife AC-300 Blood Glucose Monitoring System  
Goodlife AC-301 Blood Glucose Monitoring System  
Goodlife AC-302 Blood Glucose Monitoring System  
Goodlife AC 303 Blood Glucose Monitoring System  
Goodlife AC-304 Blood Glucose Monitoring System  
Goodlife AC-305 Blood Glucose Monitoring System  
Goodlife AC-300 Professional Blood Glucose Monitoring System  
Goodlife AC-301 Professional Blood Glucose Monitoring System  
Goodlife AC-302 Professional Blood Glucose Monitoring System  
Goodlife AC-303 Professional Blood Glucose Monitoring System  
Goodlife AC-304 Professional Blood Glucose Monitoring System  
Goodlife AC-305 Professional Blood Glucose Monitoring System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, LFR

Dated: April 15, 2015

Received: April 16, 2015

Dear Axel Lin:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Katherine Serrano -S**

For: Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-300 Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-300 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-300 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-300 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-300 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-300 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-301 Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-301 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-301 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-301 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-301 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-301 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-302 Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-302 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-302 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-302 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-302 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-302 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-303 Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-303 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-303 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-303 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-303 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-303 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-304 Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-304 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-304 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-304 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-304 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-304 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-305 Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-305 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-305 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-305 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-305 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-305 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-300 Professional Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The GoodLife AC-300 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-300 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-301 Professional Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The GoodLife AC-301 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-301 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-302 Professional Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The GoodLife AC-302 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-302 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-303 Professional Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The GoodLife AC-303 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-303 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-304 Professional Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The GoodLife AC-304 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-304 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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)

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## Indications for Use

510(k) Number (if known)  
K140150

Device Name  
GoodLife AC-305 Professional Blood Glucose Monitoring System

### Indications for Use (Describe)

The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The GoodLife AC-305 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-305 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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## 510(k) Summary

### 1. Submitter Information

Company name: HMD BioMedical Inc.  
Contact person: Axel Lin  
Address: No. 181, Minsheng St., Xinpu Township, Hsinchu  
County, Taiwan  
Phone: 886-3-6017000  
FAX: 886-3-5885500  
E-mail: axellin@hmdbio.com  
Date Prepared: MAY 14 2015

### 2. Name of Device

Trade/Proprietary Name:

For single patient use-

GoodLife AC-300 Blood Glucose Monitoring System  
GoodLife AC-301 Blood Glucose Monitoring System  
GoodLife AC-302 Blood Glucose Monitoring System  
GoodLife AC-303 Blood Glucose Monitoring System  
GoodLife AC-304 Blood Glucose Monitoring System  
GoodLife AC-305 Blood Glucose Monitoring System

For multiple patient use-

GoodLife AC-300 Professional Blood Glucose Monitoring System  
GoodLife AC-301 Professional Blood Glucose Monitoring System  
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GoodLife AC-303 Professional Blood Glucose Monitoring System  
GoodLife AC-304 Professional Blood Glucose Monitoring System  
GoodLife AC-305 Professional Blood Glucose Monitoring System

Common name: Blood Glucose Test System  
Classification name: Glucose Test System  
Classification Panel: Clinical Chemistry (75)  
Regulation no.: 862.1345 (Class II), 862.1660 (Class I)  
Product code: NBW, LFR

### 3. Predicate Device

Trade/Proprietary name:

GoodLife AC-300 Blood Glucose Monitoring System  
GoodLife AC-301 Blood Glucose Monitoring System  
GoodLife AC-302 Blood Glucose Monitoring System  
GoodLife AC-303 Blood Glucose Monitoring System  
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GoodLife AC-304 Professional Blood Glucose Monitoring System  
GoodLife AC-305 Professional Blood Glucose Monitoring System

Common name: Blood Glucose Test System  
Submitter: HMD BioMedical Inc.  
510(k) no.: K113307  
Product code: LFR, NBW, JJX

### 4. Device Description

The device description of the GL GoodLife Series Blood Glucose Monitoring System is as follows.

GL GoodLife Series Blood Glucose Monitoring System consists of:

(1) Glucose Meter (Model no.: AC-300, AC-301, AC-302, AC-303, AC-304, AC-305)

(2) Glucose Test Strips (Model no.: AC) prior 510(k) clearance K113307

(3) Two levels of glucose control solutions (L1 and L2) may be purchased separately. prior 510(k) clearance K113307

(4) Check Strip

(5) Instruction for use

GL GoodLife Series Professional Blood Glucose Monitoring System consists of:

(1) Glucose Meter (Model no.: AC-300, AC-301, AC-302, AC-303, AC-304, AC-305)

(2) Glucose Test Strips (Model no.: AC) prior 510(k) clearance K113307

(3) Two levels of glucose control solutions (L1 and L2) may be purchased separately. prior 510(k) clearance K113307

(4) Check Strip

(5) Instruction for use

These models have the same intended use and technological characteristics except the housing of the meter. Although the different shapes of housing, the materials are the same.

[Test Principle]

GL GoodLife Series Blood Glucose Monitoring System is an electrochemical biosensor system that measures the amount of electric current produced then displays the result as a blood glucose level on the LCD monitor. When the blood is drawn into the blood reaction zone of the test strip, the glucose in the blood sample mixes with a special chemical in the test strip, which produces a small electric current. The reaction current is proportional to the amount of glucose in the blood. The result is displayed on the LCD monitor and automatically stored in the meter for future use.

[Control Solution]

The GL GoodLife Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) assessing the performance of the GL GoodLife Series Blood Glucose monitoring system and GoodLife Blood Glucose Test strips (AC). There are two levels of controls (L1 and L2).

[Check Strip]

The Check Strip can be used to check that the meter is operating properly. It is composed of PCB, resistor, top cover and bottom cover.

[Device Calibration]

The device is calibrated by implicit coding process. While inserting the test strip into strip slot to perform the blood glucose test, the coding procedure is complete. The meter will apply formula including this parameter of code to calculate the glucose value.

## 5. Intended Use

For single patient use:

### GoodLife AC-300 Blood Glucose Monitoring System

The GoodLife AC-300 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-300 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-300 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-300 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-300 Blood Glucose Meter to quantitatively measure

glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

#### GoodLife AC-301 Blood Glucose Monitoring System

The GoodLife AC-301 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-301 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-301 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-301 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-301 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

#### GoodLife AC-302 Blood Glucose Monitoring System

The GoodLife AC-302 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-302 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-302 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-302 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-302 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

#### GoodLife AC-303 Blood Glucose Monitoring System

The GoodLife AC-303 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-303 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-303 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-303 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-303 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

#### GoodLife AC-304 Blood Glucose Monitoring System

The GoodLife AC-304 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-304 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-304 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-304 Blood Glucose Monitoring

System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-304 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

#### GoodLife AC-305 Blood Glucose Monitoring System

The GoodLife AC-305 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The GoodLife AC-305 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-305 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-305 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-305 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

For multiple use-

#### GoodLife AC-300 Professional Blood Glucose Monitoring System

The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-300 Professional Blood

Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-300 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-300 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

#### GoodLife AC-301 Professional Blood Glucose Monitoring System

The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-301 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-301 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

### GoodLife AC-302 Professional Blood Glucose Monitoring System

The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-302 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-302 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

### GoodLife AC-303 Professional Blood Glucose Monitoring System

The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-303 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-303 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

#### GoodLife AC-304 Professional Blood Glucose Monitoring System

The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-304 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-304 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

#### GoodLife AC-305 Professional Blood Glucose Monitoring System

The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid

to monitor the effectiveness of diabetes control. The GoodLife AC-305 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-305 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

## 6. Comparison of Subject Devices and predicate device

## Technological Characteristics Comparison Table of GL GoodLife Series Blood Glucose Monitoring System (K113307)

Similarities		
Item	Subject device GL GoodLife Series BGMS	Predicate device GL GoodLife Series BGMS (K113307)
Intended use	It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood.	Same
Detection method	Amperometry: Current produced by chemical reaction	Same
Test range	20~600mg/dL	Same
Operating conditions	50~104°F (10~40°C), 20~80%	Same
Storage Temperature	50~104°F (10~40°C), 20~80%	Same
Autocoding	Yes	Same
Enzyme	Glucose Dehydrogenase (FAD) ( <i>Aspergillus oryzae</i> )	Same
Capillary testing site	Fingertips only	Same
Sample volume	0.5ul	Same
Memory	999	Same
Test time	5 sec	Same
Average	30 days	Same
Coding function	Coding function is combined in each test strip. Coding will be done when insert the test strip to	Same

Similarities		
Item	Subject device GL GoodLife Series BGMS	Predicate device GL GoodLife Series BGMS (K113307)
	perform the glucose test.	

Differences		
Item	Subject device GL GoodLife Series	Predicate device GL GoodLife Series (K113307)
Data transmission	Near Field Communication (NFC) module (Dynamic NFC Tag)	N/A
S/N Label of Meter	With NFC logo	Without NFC logo
Bag size and the label size of foil packed strip	Adding different packing formats for 15 pcs, 100 pcs/each bag	Only one format for 50 pcs/each bag
Contents of foil packed strip	15 pcs, 50 pcs, 100 pcs/each bag	Only 50 pcs/each bag

## 7. Discussion of Clinical Tests Performed

GL GoodLife Series Blood Glucose Monitoring System (Subject Device) results of testing performed to validate changes to the system met pre-determined acceptance criteria and demonstrate that the subject device is substantially equivalent to the predicate device.

## 8. Conclusion

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.