

K 113307

JUL 27 2012

## 510(k) Summary

### 1. Submitter Information

Company name: HMD BioMedical Inc.  
Contact person: Jessica Tung  
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Date Prepared: July 10, 2012

### 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  
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

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, JJX

### 3. Predicate Device

Trade/Proprietary name: U-RIGHT TD-4279A Blood Glucose Monitoring System  
Common name: Blood Glucose Test System  
Submitter: TaiDoc Technology Corporation  
510(k) no.: K101509  
Product code: NBW, LFR

Common name: Glucose Control Solution  
Submitter: HMD Biomedical, Inc.  
510(k) no.: K032985  
Product code: JJX

### 4. Device Description

GoodLife AC-300~305 Blood Glucose Monitoring System and GoodLife AC-300~305 Professional Blood Glucose Monitoring System consist of:

- (1) Glucose Meter
- (2) Glucose Test Strips
- (3) Two levels of glucose control solutions (Level I and Level II) may be purchased separately. Glucose control solutions were previously cleared under K032985.
- (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]

GoodLife AC-300~305 Blood Glucose Monitoring System and GoodLife AC-300~305 Professional Blood Glucose Monitoring System are 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 GoodLife Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) to assess the performance of the GoodLife AC-300~305 with GoodLife AC Blood Glucose Test strips or AC-300~305 Professional Blood Glucose monitoring system with AC Professional Blood Glucose Test strips. There are two levels of controls (Levels 1,2).

[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 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-300 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-301 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-302 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-303 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-304 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-305 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-300 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-301 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-302 Professional Blood Glucose Meter and GoodLife

AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-303 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-304 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

#### 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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-305 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

6. Comparison of Subject Devices and predicate device

Technological Characteristics Comparison Table of GoodLife AC-300~305 & AC-300~305 Professional Blood Glucose Monitoring System and U-RIGHT TD-4279A Blood Glucose Monitoring System (K101509)

Item	<b>Subject Device</b> GoodLife AC-300~305 & AC-300~305 Professional BGMS	<b>Predicate Device</b> U-RIGHT TD-4279A BGMS
Similarities		
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)	Same
Test time	5 sec	Same
Capillary testing site	Fingertips only	Same

Enzyme	Glucose Dehydrogenase (FAD)	Same
Intended use	It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood	Same
Differences		
Coding function	Coding function is combined in each test strip. Coding will be done when insert the test strip to perform the glucose test.	By code strip
Sample volume	0.5ul	1.1ul
Storage condition	50~104°F (10~40°C)	35.6~89.6°F(2~32°C)
PC data transmission	N/A	USB cable

#### 7. Discussion of Clinical Tests Performed

GoodLife AC-300~305 & AC-300~305 Professional Blood Glucose Monitoring System (Subject Device) is compliant to the standard of ISO 15197:2003 In vitro diagnostic test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. All the relevant activities were performed by professionals and the results demonstrated that the predetermined acceptance criteria were fully met.

#### 8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

- (1) ISO 15197:2003 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

- (2) IEC/EN 60601-1:2005 + CORR. 1(2006) + CORR. 2(2007), EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- (3) IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility- Requirements and tests
- (4) CLSI/NCCLS EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods
- (5) CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement.
- (6) CLSI EP07-A2: Interference Testing in Clinical Chemistry
- (7) CLSI/NCCLS EP09-A2: Method Comparison and Bias Estimation Using Patient Samples
- (8) FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

## 9. 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.



HMD BioMedical Inc  
c/o Jessica Tung  
No. 181, Minsheng St  
Xinpu Township,  
Hsinchu County 305, Taiwan

10903 New Hampshire Avenue  
Silver Spring, MD 20993

JUL 27 2012

Re: k113307

Trade 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  
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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: Class II  
Product Codes: NBW, LFR, JJX  
Dated: July 20, 2012  
Received: July 23, 2012

Dear Ms Tung:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-300 Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-300 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   V  

(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) k113307

Page 1 of 12

## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-301 Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-301 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use V

(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K113307

## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-302 Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-302 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   V  

(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K113307

## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-303 Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-303 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use V  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K113307

## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-304 Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-304 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   V  

(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K113307

## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-305 Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-305 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use   V    
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-300 Professional Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-300 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use   V  

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AND/OR

Over-The-Counter Use   V  

(21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-301 Professional Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-301 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use  V

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  V

(21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-302 Professional Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-302 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use   V  

AND/OR Over-The-Counter Use   V  

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## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-303 Professional Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-303 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use  V   
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use  V   
(21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-304 Professional Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-304 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use   V  

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Over-The-Counter Use   V  

(21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): k113307

Device Name [Trade Name]:

GoodLife AC-305 Professional Blood Glucose Monitoring System

Indications for Use:

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.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-305 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use   V  

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Over-The-Counter Use   V  

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