K121433



**510(k) Summary**

FEB 14 2013

1. Submitter Information

| | |
|---|---|
| Company name: | HMD BioMedical Inc. |
| Contact person: | Jessica Tung |
| Address: | No. 181, Minsheng St., Xinpu Township, Hsinchu County, Taiwan |
| Phone: | 886-3-6017000 |
| FAX: | 886-3-5885500 |
| E-mail: | jessica-tung@hmdbio.com |
| Date Prepared: | February 14, 2013 |

2. Name of Device

Trade/Proprietary Name:

For single patient use

GoodLife CS-200 Blood Glucose Monitoring System

For multiple patient use

GoodLife CS-200 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) |
| Product code: | NBW, LFR |

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 |

4. Device Description

GoodLife CS-200 Blood Glucose Monitoring System and GoodLife CS-200 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

[Test Principle]

The GoodLife CS-200 & GoodLife CS-200 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) assessing the performance of the GoodLife CS-200 & GoodLife CS-200 Professional Blood Glucose Monitoring System and GoodLife KP & GoodLife KP 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 Digital Code Strip. While inserting the Digital Code Strip into the coding slot, the meter will turn on automatically and complete the coding. The meter will apply formula including this parameter of code to calculate the glucose value.

5. Intended Use

**The GoodLife CS-200 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 CS-200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GoodLife CS-200 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 CS-200 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes, nor for neonatal use.

The GoodLife KP Blood Glucose Test Strips are for use with the GoodLife CS-200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

**The GoodLife CS-200 Professional Blood Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose (sugar) in venous or arterial whole blood or fresh capillary whole blood drawn from the fingertips. It is intended for testing outside the body (in vitro diagnostic use) and intended for multiple-patient use in professional healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife CS-200 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes, nor for neonatal use.

The GoodLife KP Professional Blood Glucose Test Strip is for use with

the GoodLife CS-200 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in venous or arterial whole blood or fresh capillary whole blood drawn from the fingertips

6. Comparison of subject devices and predicate device

Technological Characteristics Comparison Table of GoodLife CS-200 Blood Glucose Monitoring System for single patient use & GoodLife CS-200 Professional Blood Glucose Monitoring System for multiple patient use and U-RIGHT TD-4279A Blood Glucose Monitoring System (K101509)

| Item | Subject Device<br>GoodLife CS-200 & CS-200 Professional<br>BGMS | Predicate Device<br>U-RIGHT TD-4279A<br>BGMS (k101509) |
|---|---|---|
| Similarities | | |
| Intended use | For single patient use (CS-200) –<br>It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood | Same |
| Detection method | Amperometry:<br>Current produced by chemical reaction | Same |
| Coding function | By code strip | Same |
| Test range | 20~600mg/dL | Same |
| Operating conditions | 50~104°F (10~40°C) | Same |
| Test time | 5 sec | Same |
| Capillary testing site | For single patient use (CS-200) -<br>Fingertips only | Same |
| Enzyme | Glucose Dehydrogenase (FAD) | Same |
| Differences | | |
| Intended use | For multiple patient use (CS-200 Professional) –<br>It is designed to quantitatively measure the concentration of glucose in fresh capillary drawn from the fingertips, venous or | It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood. |

| | | |
|---|---|---|
| | arterial whole blood samples. | |
| 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 CS-200 Blood Glucose Monitoring System and GoodLife CS-200 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. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 25, 2013

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

Re: k121433
Trade/Device Name: GoodLife CS-200 Blood Glucose Monitoring System
GoodLife CS-200 Professional Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: LFR, NBW
Dated: February 07, 2013
Received: February 8, 2013

Dear Ms. Tung:

This letter corrects our substantially equivalent letter of February 14, 2013.

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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -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 Form

510(k) Number (if known): k121433

Device Name: GoodLife CS-200 Blood Glucose Monitoring System

Indications for Use:

The GoodLife CS-200 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 CS-200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GoodLife CS-200 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 CS-200 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife KP Blood Glucose Test Strips are for use with the GoodLife CS-200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k121433

# Indications for Use Form

510(k) Number (if known): k121433

Device Name: GoodLife CS-200 Professional Blood Glucose Monitoring System

Indications for Use:

The GoodLife CS-200 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in venous or arterial whole blood or fresh capillary whole blood drawn from the fingertips. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife CS-200 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife KP Professional Blood Glucose Test Strip is for use with the GoodLife CS-200 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in venous or arterial whole blood or fresh capillary drawn from the fingertips.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k121433