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

June 7, 2017

TIANJIN EMPECS MEDICAL DEVICE CO., LTD.
C/O PRISCILLA CHUNG
LK CONSULTING GROUP USA, INC.
690 ROOSEVELT
IRVINE, CA 92620

Re: K162564
Trade/Device Name: Medisign GH81 Blood Glucose Monitoring System
Medisign GH82 Blood Glucose Monitoring System
Medisign GH83 Blood Glucose Monitoring System
Medisign GH81 BT Blood Glucose Monitoring System
Medisign GH82 BT Blood Glucose Monitoring System
Medisign GH83 BT Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: May 4, 2017
Received: May 5, 2017

Dear Priscilla Chung:

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,

Kellie B. Kelm -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162564

Device Name
Medisign GH81 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign GH81 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH81 Blood Glucose Monitoring System is comprised of the Medisign GH81 Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162564

Device Name
Medisign GH82 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign GH82 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH82 Blood Glucose Monitoring System is comprised of the Medisign GH82 Blood Glucose Meter and Medisign GH82 Blood Glucose Test Strips.

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162564

Device Name
Medisign GH83 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign GH83 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH83 Blood Glucose Monitoring System is comprised of the Medisign GH83 Blood Glucose Meter and Medisign GH83 Blood Glucose Test Strips.

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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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162564

Device Name
Medisign GH81 BT Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign GH81 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH81 BT Blood Glucose Monitoring System is comprised of the Medisign GH81 BT Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

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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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162564

Device Name
Medisign GH82 BT Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign GH82 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH82 BT Blood Glucose Monitoring System is comprised of the Medisign GH82 BT Blood Glucose Meter and Medisign GH82 Blood Glucose Test Strips.

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162564

Device Name
Medisign GH83 BT Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign GH83 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH83 BT Blood Glucose Monitoring System is comprised of the Medisign GH83 BT Blood Glucose Meter and Medisign GH83 Blood Glucose Test Strips.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

1. 510(k) Number

K162564

2. Date Prepared

June 06, 2017

3. Applicant

Tianjin Empecs Medical Device Co., Ltd.
No.35 and 37, Yingcheng street, Hangu, Binhai New Area, Tianjin, 300480 China
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4. Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
690 Roosevelt, Irvine CA 92606
Tel. 714-202-5789
Email: juhee.c@lkconsultinggroup.com

5. Measurement

Glucose in fresh capillary whole blood

6. Type of Test

Quantitative, Amperometric detection, Flavin adenine dinucleotide-Glucose dehydrogenase (FAD-GDH)

7. Device Name

Medisign® GH81 Blood Glucose Monitoring System
Medisign® GH82 Blood Glucose Monitoring System
Medisign® GH83 Blood Glucose Monitoring System

Medisign® GH81 BT Blood Glucose Monitoring System
Medisign® GH82 BT Blood Glucose Monitoring System
Medisign® GH83 BT Blood Glucose Monitoring System

8. Common Classification Name

Blood Glucose Test System

9. Classification

Product Code	Classification	Regulation Section	Panel
NBW - System, Test, Blood Glucose, Over The Counter	Class II	21 CFR § 862.1345	75-Chemistry
LFR - Glucose dehydrogenase, glucose test system	Class II	21 CFR § 862.1345	75-Chemistry

10. Predicate Device Information

Device Name: OneTouch Verio Flex Blood Glucose Monitoring System
510(k) Number: k150214

11. Indications for Use

Medisign®GH81 Blood Glucose Monitoring System

The Medisign GH81 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH81 Blood Glucose Monitoring System is comprised of the Medisign GH81 Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

Medisign®GH82 Blood Glucose Monitoring System

The Medisign GH82 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH82 Blood Glucose Monitoring System is comprised of the Medisign GH82 Blood Glucose Meter and Medisign GH82 Blood Glucose Test Strips.

Medisign®GH83 Blood Glucose Monitoring System

The Medisign GH83 Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis

of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH83 Blood Glucose Monitoring System is comprised of the Medisign GH83 Blood Glucose Meter and Medisign GH83 Blood Glucose Test Strips.

Medisign® GH81 BT Blood Glucose Monitoring System

The Medisign GH81 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH81 BT Blood Glucose Monitoring System is comprised of the Medisign GH81 BT Blood Glucose Meter and Medisign GH81 Blood Glucose Test Strips.

Medisign® GH82 BT Blood Glucose Monitoring System

The Medisign GH82 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH82 BT Blood Glucose Monitoring System is comprised of the Medisign GH82 BT Blood Glucose Meter and Medisign GH82 Blood Glucose Test Strips.

Medisign® GH83 BT Blood Glucose Monitoring System

The Medisign GH83 BT Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm and forearm. It is intended for self-testing outside the body (in-vitro diagnostics use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended for single patient use only and should not be shared. It is not to be used for the diagnosis of or screening of diabetes, or for neonatal use. Alternative site testing (palm and forearm) should be done only during steady-state times (when glucose is not changing rapidly).

The Medisign GH83 BT Blood Glucose Monitoring System is comprised of the Medisign GH83 BT Blood Glucose Meter and Medisign GH83 Blood Glucose Test Strips.

12. Device Description

The Medisign GH81, GH82, GH83, GH81 BT, GH82 BT, and GH83 BT Blood Glucose Monitoring System quantitatively measures the glucose in the whole blood sample by using a harmless electrical current produced by a chemical reaction between the glucose in the blood and Flavin adenine dinucleotide-Glucose dehydrogenase (FAD-GDH) on the test strip. This current is

proportionally converted to the amount of glucose in the blood sample to display as the blood glucose result. Glucose measurements from this system are reported as plasma equivalents.

The Medisign GH81, GH82, GH83, GH81 BT, GH82 BT, GH83 BT Blood Glucose Monitoring Systems are for over-the-counter use and systems' kit basically consist of a blood glucose meter, blood glucose test strips, a lancing device, sterile lancets, a carrying case, however some kits may not have test strips or a lancing device or sterile lancets. The Medisign GH81, GH82, GH83 Blood Glucose Monitoring System allows to transmit blood glucose test results to a PC via an external USB cable and Medisign GH81 BT, GH82 BT, GH83 BT Blood Glucose Monitoring System can transmit blood glucose test results to a PC via an external USB cable or a Bluetooth Low Energy transmitter in meter.

The Medisign GH81 Blood Glucose Test Strip is for the Medisign GH81 and GH81 BT Blood Glucose Meter. The Medisign GH82 Blood Glucose Test Strip is for the Medisign GH82 and GH82 BT Blood Glucose Meter. The Medisign GH83 Blood Glucose Test Strip is for the Medisign GH83 and GH83 BT Blood Glucose Meter.

Each of test strip box may contain 10 test strips or 25 test strips or 50 test strips with one vial or 50 test strips split into two vials. Also, test strip box may contain 25 or 50 test strips packed separately for each test strip.

The Medisign Link Diabetes Management Software is an optional software accessory and were previously cleared in k133260.

13. Comparison with the Predicate Device

Similarities		
Features	**Predicate Device (k150214) OneTouch Verio Flex Blood Glucose Monitoring System**	**Subject Device (K162564) Medisign GH81, GH82, GH83**
Intended Use	Intended to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertip, palm or forearm and in venous whole blood as an aid in monitoring the effectiveness of glucose control.	Refer to the aforementioned Intended Use
Enzyme	FAD-GDH	Same
Test Principle	Amperometry	Same
Calibration	Plasma equivalent	Same
Test Sample	Capillary whole blood	Same
Operating Temperature	50 ~ 104ºF	Same
Operating Humidity	10 ~ 90%RH	Same
Hematocrit Range	20 ~ 60%	Same
Measuring Range	20 ~ 600 mg/dL	Same
Memory Capacity	500 test result	Same
Differences		
Measuring Time	5 seconds	6 seconds
Battery	One 3.0V Lithium batteries(CR2032)	Two 3.0V Lithium batteries(CR2032)
Coding of Test Strip	Non-Coding	Auto coding
Sample Volume	0.4 μℓ	0.5 μℓ
Averaging Results	7,14,30 and 90 days	7,14 and 30 days
Alternative Site	Not Available	Palm and forearm
Pre/Post-meal flagging	Not available	Available
Test Strip Ejector	Not available	Available
Range Indicator	Available	Not available

Data Download	USB or Bluetooth Low Energy	USB

Similarities		
Features	**Predicate Device (k150214) OneTouch Verio Flex Blood Glucose Monitoring System**	**Subject Device (K162564) Medisign GH81 BT, GH82 BT, GH83 BT**
Intended Use	Intended to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertip, palm or forearm and in venous whole blood as an aid in monitoring the effectiveness of glucose control.	Refer to the aforementioned Intended Use
Enzyme	FAD-GDH	Same
Test Principle	Amperometry	Same
Calibration	Plasma equivalent	Same
Test Sample	Capillary whole blood	Same
Operating Temperature	50 ~ 104ºF	Same
Operating Humidity	10 ~ 90%RH	Same
Hematocrit Range	20 ~ 60%	Same
Measuring Range	20 ~ 600 mg/dL	Same
Memory Capacity	500 test result	Same
Data Download	USB or Bluetooth Low Energy	Same
Differences		
Measuring Time	5 seconds	6 seconds
Battery	One 3.0V Lithium batteries(CR2032)	Two 3.0V Lithium batteries(CR2032)
Coding of Test Strip	Non-Coding	Auto coding
Sample Volume	0.4 μℓ	0.5 μℓ
Averaging Results	7,14,30 and 90 days	7,14 and 30 days
Alternative Site	Not Available	Palm and forearm
Pre/Post-meal flagging	Not available	Available
Test Strip Ejector	Not available	Available

Range Indicator	Available	Not available

14. Performance Test Summary

The clinical and non-clinical tests were conducted and demonstrated the performance of the candidate devices were satisfied with all pre-determined acceptance criteria. The candidate devices were compared with the YSI 2300 STAT Plus as a reference instrument to evaluate the system reliability and accuracy performance. No adverse events pertaining to the safety and effectiveness occurred during the tests.

15. Performance Test Summary

Design verification and validation tests for the candidate devices having the same intended use, fundamental scientific technology and performance characteristics as the predicate device have demonstrated and confirmed that the performance, safety and effectiveness are satisfied with those of the predicate device. Therefore, the candidate devices can be considered substantially equivalent to the predicate device cleared under k150214.