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

JOINSOON MEDICAL TECHNOLOGY CO, LTD.
MARIA GRIFFIN
SENIOR CONSULTANT
55 NORTHERN BLVD, SUITE 200
GREAT NECK NY 11021

October 13, 2015

Re: K140325
Trade/Device Name: Joinsoon® EON L Glucose Monitoring System
Joinsoon® E0N LS Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: September 22, 2015
Received: September 24, 2015

Dear Maria Griffin:

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

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)*
K140325

Device Name
Joinsoon® EON L Glucose Monitoring System

Indications for Use *(Describe)*
The Joinsoon® EON L Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® EON L Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes in a home setting as an aid to monitor the effectiveness of diabetes control. The Joinsoon® EON L Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The Joinsoon® EON L Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Joinsoon® Single Strips are for use with the Joinsoon® EON L Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® Control Solution is for use with the Joinsoon® EON L Glucose Meter and Joinsoon® Single Strips as a quality control check to verify that the meter and test strips are working together properly, and that the test is performing correctly.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K140325

Device Name
Joinsoon® EON LS Glucose Monitoring System

Indications for Use *(Describe)*
The Joinsoon® EON LS Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® EON LS Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes in a home setting as an aid to monitor the effectiveness of diabetes control. The Joinsoon® EON LS Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The Joinsoon® EON LS Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Joinsoon® Snap Strips are for use with the Joinsoon® EON LS Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® Control Solution is for use with the Joinsoon® EON LS Glucose Meter and Joinsoon® Snap Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

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 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K140325 .

1. Submitter's Identification:

Joinsoon Medical Technology Co. Ltd.
19F, No 79, Sec. 1
Shintai 5th Road
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Taiwan
Phone: +886 2 26984882
Fax: +886 2 26984883

Contact person: Dr. Jen Fang Lee, Vice President

Date Summary Prepared: 9/21/2015

2. Trade Name of the Device:

Joinsoon® EON LS Glucose Monitoring System which includes Joinsoon® EON LS Blood Glucose Meter, Joinsoon® Snap Strips and Joinsoon® Control Solutions.

Joinsoon® EON L Glucose Monitoring System which includes Joinsoon® EON L Blood Glucose Meter, Joinsoon® Single Strips and Joinsoon® Control Solutions.

3. Common or Usual Name and classification:

Common Name: glucose test system (OTC)
Regulation: 862.1345
Product Code: NBW

Common Name: Quality Control Material (assayed and unassayed)
Regulation: 862.1660
Product Code: JJX

Common Name: Glucose Oxidase
Regulation: 862.1345
Product Code: CGA

4. Predicate Device Information:

Lifescan OneTouch® Select Glucose Monitoring System K072543

5. Device Description:

The Joinsoon® EON LS Glucose Monitoring system consists of: a Joinsoon® EON LS Glucose Meter and Joinsoon® Snap Strips. The Joinsoon® EON L Glucose Monitoring system consists of: a Joinsoon® EON L Glucose Meter and Joinsoon® Single Strips.
Both systems utilize an electrochemical – method based meter and dry reagent biosensor (test strip) for blood glucose testing. The electron accumulates on the electrode when glucose reacts with the reagent on the electrode. A current can be detected by the Joinsoon® EON LS and EON L glucose meters when a constant voltage is applied across the electrodes. The current will be converted into glucose concentration by an embedded transfer function in the meter. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

The Joinsoon® Snap Strips utilize the enzyme glucose oxidase. There is no-coding needed for use of the meter and test strips. The Joinsoon® Snap Strip has 10 individual test sections which can be used one at a time with the Joinsoon® EON LS Glucose Meter. Each test section has its own Reaction Zone with the Enzyme at one end, and contact pads at the other end.

The Single Strips utilize the enzyme glucose oxidase. There is no-coding needed for use of the meter and test strips.

The Joinsoon® EON L Glucose Monitoring system is sold with the following components: Joinsoon® EON L Glucose Meter, Joinsoon® Single Strips, control solution, lancet, lancing device, quick start user guide, user manual, warranty card and a carrying case.

The Joinsoon® EON LS Glucose Monitoring system is sold with the following components: Joinsoon® EON LS Glucose Meter, Joinsoon® Snap Strips, control solution, lancet, lancing device, quick start user guide, user manual, warranty card and a carrying case.

6. Indications for Use (Joinsoon® EON LS Glucose Monitoring System):

The Joinsoon® EON LS Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® EON LS Glucose Monitoring System is intended for self-testing outside the body (in vitro diagonostic use) by people with diabetes in a home setting as an aide to monitor the effectiveness of diabetes control. The Joinsoon® EON LS Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonateal use.

The Joinsoon® EON LS Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Joinsoon® Snap Strips are for use with the Joinsoon® EON LS Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® Control Solution is for use with Joinsoon® EON LS Glucose Meter and Joinsoon® Snap Strips as a quality control check to verify that the meter and test strip are working together

properly, and that the test is performing correctly.

Indications for Use (Joinsoon® EON L Glucose Monitoring System):
The Joinsoon® EON L Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® EON L Glucose Monitoring System is intended for self-testing outside the body (in vitro diagonostic use) by people with diabetes in a home setting as an aide to monitor the effectiveness of diabetes control. The Joinsoon® EON L Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonateal use.

The Joinsoon® EON L Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Joinsoon® Single Strips are for use with the Joinsoon® EON L Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The Joinsoon® Control Solution is for use with Joinsoon® EON L Glucose Meter and Joinsoon® Single Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

7. Special condition for use statement(s):

The Joinsoon® Snap Strips and Joinsoon® Control Solution are to be used only with the Joinsoon® EON LS Blood Glucose Meter to test glucose in finger stick capillary whole blood only. This meter is not to be used for Alternate Site Testing or Neonatal Testing

The Joinsoon® Single Strips and Joinsoon® Control Solution are to be used only with the Joinsoon® EON L Blood Glucose Meter to test glucose in finger stick capillary whole blood only. This meter is not to be used for Alternate Site Testing or Neonatal Testing.

8. Technological Comparison to Predicate Devices:
The Joinsoon® EON L and EON LS Blood Glucose Test systems utilize the same technology as the predicate device. The similarities and differences between the devices can be seen in the chart below:

Item description	**Joinsoon EON LS Glucose Monitoring**	**Joinsoon EON L Glucose Monitoring**	**OneTouch Select Glucose**
Indications for Use	Difference in test site:	Difference in test site: Fingertip only	Difference in test sites: alternate
Setting	At home	At home	At home and in a clinical
Method	Amperometry	Amperometry	Same
Assay Method	Glucose Oxidase	Glucose Oxidase	Glucose Oxidase
Memory	1000 blood and 250	1000 blood and 250	350 blood or control
Sample Type	Fresh capillary	Fresh capillary whole	Fresh capillary whole
Strip Coding	No Coding	No Coding	Coding required
Result range	20 mg/dL to 600	20 mg/dL to 600 mg/dL	20 mg/dL to 600 mg/dL
Test Time	4 sec	4 sec	5 sec

Calibration	Plasma-equivalent	Plasma-equivalent	Plasma-equivalent
Power Required	3V Lithium CR2032	3V Lithium CR2032 Coin	3V Lithium CR2032 Coin
Test Strip Type	Snap Strips with 10	Single Use	Single Use
Enzyme	Glucose Oxidase	Glucose Oxidase	Glucose Oxidase
Hematocrit	30%~55%	30%~55%	30%~55%
Sample Volume	0.8µl	0.8µl	1.0µl

Similarity and Difference of the Control Solutions		
Item description	**Joinsoon Control Solutions**	**OneTouch Select Control Solutions**
Indications for Use	To check that the glucose meter and test strips are working together properly and that the test is performing correctly.	Same
Matrix	Viscosity-adjusted, aqueous liquid.	Same
Number of Levels	3 Levels	2 Levels

Discussion of substantial equivalence:

The main differences are that the Joinsoon® EON LS and EON L Glucose Monitoring systems does not require coding and the predicate device uses coding. The user study shows that this difference does not impact the performance of the device. In addition, the predicate only provides for the use of two levels of control solution whereas the Joinsoon® EON LS and EON L Glucose Monitoring Systems provide a third control solution for use. This does not raise any new concern for safety or effectiveness as it provides for an additional level of control testing. Joinsoon® EON LS and EON L Glucose Monitoring systems are also able to store more glucose readings than the predicate device. This feature does not pose any new safety or effectiveness risk to the user per the Software V&V testing.

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

The Joinsoon® EON LS and EON L Glucose Monitoring systems were tested according non-clinical tests including the following standards:

Description	**Standard reference**
Electromagnetic Compatibility/ESD	IEC 61326-1:2005 IEC 61326-2-6:2005 IEC 60601-1-2:2007
Emission	CISPR 11:2009+A1:2010 (Class B)
Immunity	IEC 61000-4-2:2008; IEC 61000-4-3:2010; IEC 61000-4-6:2008; IEC 61000-4-8:2009
Linearity	CLSI EP6-A
Interference	CLSI EP7-A2
Traceability	ISO 17511:2003
Stability Test	CLSI EP25-A
Precision	CLSI EP5-A2

The studies were performed by third party laboratories or by qualified personnel as referenced in the supporting documentation in the submission. All of the evaluated performances met the pre-determined acceptance criteria set in the study protocol.

10. Discussion of Clinical Tests Performed:

The accuracy study was performed by comparing whole blood (plasma equivalent) glucose values on the Joinsoon® EON LS and EON L Glucose Monitoring Systems, the predicate device and a lab instrument. A total of 150 participants were studied. The results demonstrated that the Joinsoon® EON LS and EON L Glucose Monitoring Systems met the acceptance criteria.

A user study was performed to demonstrate that lay users could use the Joinsoon® EON LS and EON L Glucose Monitoring Systems and obtain accurate results. The study was performed by 150 users. The results of the study met the acceptance criteria.

11. Conclusions:

In conclusion, based on the acceptable results of the testing we conclude that the Joinsoon® EON LS and EON L Glucose Monitoring systems are substantially equivalent to the predicate device.