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

March 21, 2017

TIANJIN EMPECS MEDICAL DEVICE CO., LTD.
C/O JIGAR SHAH
MDI CONSULTANTS, INC.
55 NORTHERN BLVD., SUITE 200
GREAT NECK NY 11021

Re: K152534
Trade/Device Name: Medisign MM1000 BT Blood Glucose Monitoring System,
Medisign MM1100 BT Blood Glucose Monitoring System,
Medisign MM1200 BT Blood Glucose Monitoring System,
Smart Diabetes Bluetooth Blood Glucose Monitoring System,
Medisign MM 1000 BT Multi Blood Glucose Monitoring System,
Medisign MM 1100 BT Multi Blood Glucose Monitoring System,
Medisign MM 1200 BT Multi Blood Glucose Monitoring System,
Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: March 17, 2017
Received: March 20, 2017

Dear Jigar Shah:

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
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)*
K152534

Device Name
Medisign MM1000 BT Blood Glucose Monitoring System

Indications for Use *(Describe)*
Medisign MM1000 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 by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Medisign MM1000 Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1000 BT Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

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.

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)*
K152534

Device Name
Medisign MM1100 BT Blood Glucose Monitoring System

Indications for Use *(Describe)*

Medisign MM1100 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 by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Medisign MM1100 Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1100 BT Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

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

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

510(k) Number *(if known)*
K152534

Device Name
MM1200 BT Blood Glucose Monitoring System

Indications for Use *(Describe)*

Medisign MM1200 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 by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Medisign MM1200 Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1200 BT Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

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)*
K152534

Device Name
Smart Diabetes Bluetooth Blood Glucose Monitoring System

Indications for Use *(Describe)*
Smart Diabetes Bluetooth Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Smart Diabetes Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Smart Diabetes Bluetooth Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Smart Diabetes Glucose Control Solutions are intended for use with the Smart Diabetes Bluetooth meter and Smart Diabetes test strips as a quality control check to verify that the meter and test strips are working properly together.

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)*
K152534

Device Name
Medisign MM1000 BT MULTI Blood Glucose Monitoring System

Indications for Use *(Describe)*
Medisign MM1000 BT MULTI Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Medisign MM1000 MULTI Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1000 BT MULTI Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

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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510(k) Number *(if known)*
K152534

Device Name
Medisign MM1100 BT MULTI Blood Glucose Monitoring System

Indications for Use *(Describe)*
Medisign MM1100 BT MULTI Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Medisign MM1100 MULTI Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1100 BT MULTI Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

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

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See PRA Statement below.

510(k) Number *(if known)*
K152534

Device Name
Medisign MM1200 BT MULTI Blood Glucose Monitoring System

Indications for Use *(Describe)*
Medisign MM1200 BT MULTI Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Medisign MM1200 MULTI Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1200 BT MULTI Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

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)*
K152534

Device Name
Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System

Indications for Use *(Describe)*
Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Smart Diabetes Pro Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Smart Diabetes Bluetooth Pro Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Smart Diabetes Glucose Control Solutions are for use with both the Smart Diabetes Bluetooth Pro meter and Smart Diabetes test strips as a quality control check to verify that the meter and test strips are working properly together.

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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510(K) SUMMARY

The assigned 510(k) number is: K152534

Date Summary Prepared: March 9, 2016

1. Submitter's Identification:

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

Tel: +86(0)22-2569-6839

Contact Person:

Jigar Shah
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

2. Name of the Device:

Proprietary Names:

- Medisign® MM1000 BT Blood Glucose Monitoring System
- Medisign® MM1100 BT Blood Glucose Monitoring System
- Medisign® MM1200 BT Blood Glucose Monitoring System
- Smart Diabetes Bluetooth Blood Glucose Monitoring System
- Medisign® MM1000 BT MULTI Blood Glucose Monitoring System
- Medisign® MM1100 BT MULTI Blood Glucose Monitoring System
- Medisign® MM1200 BT MULTI Blood Glucose Monitoring System
- Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System

Common or Usual Name: Glucose Test System

Classification Name: Class II, 21 CFR 862.1345, Glucose Test System
Class I, 21 CFR 862.1660, Quality Control Material

Product code: NBW, CGA and JJX

3. Predicate Device Information:

K111456 Medisign® Blood Glucose Monitoring System

4. Device Description:

Medisign® Blood Glucose Monitoring System measures the glucose in the fresh capillary whole blood sample by using a small electrical current produced by chemical reaction between glucose in the blood and glucose oxidase 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 are reported as plasma equivalents. Blood glucose results from test strips that are plasma-equivalent are approximately 11% higher than those obtained with whole-blood equivalent test strips.

Medisign® MM 1000 BT Blood Glucose Monitoring System, Medisign® MM 1100 BT Blood Glucose Monitoring System, Medisign® MM1200 BT and Smart Diabetes Bluetooth Blood Glucose Monitoring System are basically provided with a blood glucose meter and a carrying bag including user manual, quick reference manual and log book. Blood glucose test strips (10T, 25T, 50T), blood glucose control solutions (Level 1, Level 2, Level 3), lancing device, lancets, batteries (CR2032), diabetes management software, and data transporting cable are sold separately.

Medisign® MM1000 BT MULTI Blood Glucose Monitoring System, Medisign® MM 1100 BT MULTI Blood Glucose Monitoring System, Medisign® MM1200 BT MULTI and Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System are basically provided with a blood glucose meter and a carrying bag including user manual, quick reference manual. Disposable lancing device, blood glucose test strips (10T, 25T, 50T), blood glucose control solutions (Level 1, Level 2, Level 3), batteries (CR2032) diabetes management software, and data transporting cable are sold separately.

Each box of test strips contains one vial of 10 test strips, one vial of 25 test strips, one vial of 50 test strips, or two vials of 25 test strips. Each test strip contains the following reagent compositions: glucose oxidase (A. Niger) -2.5 units, redox mediator - 32.3 µg and buffer & non-reactant - 50.5µg

Each box of control solutions (Level 1, Level 2 and Level 3) contains one vial of aqueous control solution (4ml each): Level 1 contains 0.03% concentrations of glucose (approximately 40 mg/dL), Level 2 contains 0.11% concentrations of glucose (approximately 85 mg/dL) and Level 3 contains 0.23% concentrations of glucose (approximately 260 mg/dL).

The system contains Bluetooth wireless technology. This device complies with U.S. federal guidelines, Part 15 of the FCC Rules for devices with RF capability. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesirable operation.

The Bluetooth wireless technology is used to transfer meter test results to a mobile APP.

5. Intended Use:

<For single patient use>

Medisign MM1000 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 by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Medisign MM1000 Blood Glucose Test Strips are to be used for monitoring glucose concentration

of fresh capillary whole blood with Medisign MM1000 BT Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Medisign MM1100 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 by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Medisign MM1100 Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1100 BT Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Medisign MM1200 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 by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Medisign MM1200 Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1200 BT Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Smart Diabetes Bluetooth Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes. It is intended for self testing by persons at home, for single patient use only, and should not be shared. It is intended for use outside the body (in-vitro diagnostic use only) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly).

The Smart Diabetes Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Smart Diabetes Bluetooth Blood Glucose Meter. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The test strips are intended for self testing by individuals at home, are for single-patient use only, and should not be shared. The test strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Smart Diabetes Glucose Control Solutions are intended for use with Smart Diabetes Bluetooth meter and Smart Diabetes test strips as a quality control check to verify that the meter and test strips are working properly together.

<For multiple patient use>

Medisign MM1000 BT MULTI Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Medisign MM1000 MULTI Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1000 BT MULTI Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Medisign MM1100 BT MULTI Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Medisign MM1100 MULTI Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1100 BT MULTI Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Medisign MM1200 BT MULTI Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Medisign MM1200 MULTI Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Medisign MM1200 BT MULTI Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-

disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System is intended for the quantitative measurement of the glucose in fresh capillary whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in a professional healthcare setting. It is intended for use outside the body (in-vitro diagnostic use) and not for the diagnosis of or screening for diabetes or for neonatal use. The alternative site testing (palm and forearm) should be done only during steady state times (when glucose is not changing rapidly). Only auto-disabling, single use lancing devices should be used with this system.

The Smart Diabetes Pro Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Smart Diabetes Bluetooth Pro Blood Glucose Meter. The test strips and associated meter are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system. The strips are not for the diagnosis of or screening for diabetes or for neonatal use.

Smart Diabetes Glucose Control Solutions are for use with the Smart Diabetes Bluetooth Pro meter and Smart Diabetes test strips as a quality control check to verify that the meter and test strips are working properly together.

6. Comparison to Predicate Devices:

Similarities			
Features	**Predicate Device (K111456)**	**Candidate Device**	**SE Decision**
Intended Use	Refer to the Intended Use Section	Same	SE
Enzyme	Glucose Oxidase (*Aspergillus Niger*)	Same	SE
Test Principle	Electrochemical reaction	Same	SE
Test Sample	Fresh capillary whole blood	Same	SE
Electrode Material	Carbon	Same	SE
Coding of Test Strip	Auto coding	Same	SE
Calibration	Plasma equivalent	Same	SE
Operating Temperature	50 – 104ºF	Same	SE
Operating Humidity	10 – 90%RH	Same	SE

Hematocrit Range	30 – 55%	Same	SE
Alternate Site Testing Site	Palm, Forearm	Same	SE
Measuring Time	5 seconds	Same	SE
Sample Volume	Minimum 0.5 micro liter	Same	SE
Measuring Range	20 - 600 mg/dL	Same	SE
Pre/Post-meal flagging	Available	Same	SE
Battery Life	Approximately more than 1,000 tests	Same	SE
Battery	Two(2) 3.0V Lithium batteries (CR2032)	Same	SE
Test Strip Ejector	Available	Same	SE
Memory Capacity	300 results with date, time and flags	Same	SE
Averaging Results	14 days	Same	SE
Differences			
Data Transporting Features	USB Cable (RS232)	▪ USB Cable (RS232) ▪ Wireless (Bluetooth 4.0)	-
Meter Exterior Color	-	Meter exterior color has been changed (refer to the Description of the Modification attached for the meter exterior colors).	-
Meter Display Icon	-	▪ Modification of Mute icon ▪ Adding Bluetooth icon	-
New control solution trade name	-	▪ Smart Diabetes Glucose Control Solution for use with Smart Diabetes Bluetooth Blood Glucose Monitoring System and Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System	-

7. Discussion of Performance Tests:

The modified device has the same intended use, fundamental scientific technology and performance characteristics as the predicate device. Therefore, the performance, safety and

effectiveness have not been changed from the predicate device. However, to confirm these changes have not brought any unexpected functional failure or adverse effect, verification tests were conducted as mentioned in Design Control Activity Summaries.

8. Conclusions:

Based on the outcome of the verification testing conducted, the modified subject device is substantially equivalent to the predicate device.