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

May 2, 2017

BIONIME CORPORATION
% NINA PELED, PH.D., M.B.A., REGULATORY CONSULTANT
MEDICAL DEVICE REGULATORY CONSULTANTS
627 16TH AVE.
MENLO PARK, CA 94025

Re: K161790
Trade/Device Name: iGlucose Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: March 23, 2017
Received: March 29, 2017

Dear Dr. Peled:

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 and Part 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 regulation (21 CFR Part 801 and Part 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,

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)*
K161790

Device Name
iGlucose Blood Glucose Monitoring System

Indications for Use *(Describe)*
The iGlucose 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. The iGlucose Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The iGlucose 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 iGlucose Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

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

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."

SECTION 10: EXECUTIVE 510(k) SUMMARY

SECTION 10: EXECUTIVE 510(k) SUMMARY

Assigned 510(k) Number: **k161790**

1. **Submitter Information**

Company: Bionime Corporation
No.100, Sec. 2, Daqing St., South Dist.,
Taichung City 40242, Taiwan (R.O.C.)

Contact Person: Nina Peled
Regulatory Consultant to the Bionime Corporation
627 16th Ave.
Menlo Park, CA 94025
npeled@yahoo.com
650 454 0322

2. **Date Prepared:** September 9, 2016

3. **Device Name:** iGlucose Blood Glucose Monitoring System

4. **Product Code, Class, Regulation Number and Panel**

Product Code	Class	Regulation Number	Panel
NBW; System, Test, Blood Glucose, OTC	Class II	21.CFR 862.1345	Clinical chemistry
CGA; Glucose Oxidase, Glucose	Class II	21.CFR 862.1345	Clinical chemistry

5. **Predicate Device**: GE Blood Glucose Monitoring System 333 (listed in FDA's database as Ge333 Blood Glucose Monitoring System), k143387

6. **Device Description and Principle of Operation:**

The iGlucose Blood Glucose Monitoring System consists of the iGlucose meter, the iGlucose test strips and the Rightest Glucose Control Solutions (GC550 level 2 and 4 (previously cleared under k092052). Bionime is seeking FDA's clearance to market and commercially distribute in the United States the iGlucose Blood Glucose Meter and its corresponding iGlucose Test Strips.

The iGlucose meter is an electronic device that utilizes electrical characteristics technology. When used with its corresponding iGlucose Test Strips, it quantitatively measures glucose in a small drop of fresh capillary whole blood (minimum 0.75 µL). The blood drop is placed on the test strip where it interacts with reagents in the presence of

glucose oxidase to produce an electrical current proportional to the amount of glucose in the sample. The oxidase electrochemical sensor of the meter measures the current and using meter software converts it to the corresponding glucose concentration. The glucose result is then displayed on the meter within 5 seconds.

Other system components include:

- Rightest lancing device labeled for "Single Patient Use only" as well as its disposable sterile lancets.
  FMK; Lancet, Blood, Class I, 21.CFR 878.4800, General & Plastic Surgery
- Meter charger and cable
- A clear cap for the lancing device

7. Indications for Use:

The iGlucose 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. The iGlucose Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The iGlucose 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 iGlucose Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

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

8. Special Conditions for Use Statement

- The glucose meter and lancing device are for single patient use. Do not use on multiple patients. Do not share meter with anyone including other family members.
- Do not use the lancing device for assisted blood draws by healthcare providers or at healthcare provision sites and do not share it with anyone else, even a family member.
- The iGlucose Blood Glucose Monitoring System is not for use on neonates and should not be used in the critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.
- Do not reuse; each Test Strip is for single use only.
- Do not test samples other than fresh capillary whole blood obtained from the fingertip.

- Inaccurate test results may be obtained at altitudes greater than 10,000 ft above sea level.
- Do not perform the blood glucose test at temperatures below 10°C (50°F) or above 40°C (104°F), nor below 10% or above 90% relative humidity.
- Hematocrits below 20% may cause higher results. Hematocrits above 60% may cause lower results.
- High concentrations of Uric acid >9 mg/dL, Cholesterol >600 mg/dL, and Ascorbic acid (Vitamin C) >5 mg/dL may interfere with the glucose test causing inaccurate test results.
- iGlucose Blood Glucose Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- The iGlucose Blood Glucose Monitoring System should not be used to screen for or diagnose diabetes mellitus.
- For single-patient use only.

9. Comparison to the Predicate Device

The iGlucose Blood Glucose Monitoring System is a modified version of a cleared device, the GE Blood Glucose Monitoring System 333, k143387. The modifications to the cleared device include replacing the Bluetooth data telecommunication with a cell enabled transmission (GSM) as well as some minor customer convenience upgrades.

The comparison table below outlines the similarities and differences between the subject device, the iGlucose Blood Glucose Monitoring System, and the GE Blood Glucose Monitoring System 333 serving as the predicate device:

Similarities	
Fundamental Scientific Technology of the Device	Oxidase Electrochemical Sensor. The structure, function and performance of the blood glucose monitoring module of the meter and the structure, function and performance of its accompanying test strips is unchanged between the subject device and the predicate device.
Analyte	Glucose
Measuring Range	20-600 mg/dL
Sample	Fresh capillary whole blood
Sample Volume	0.75 µL minimum
Strip Reagents	1.Glucose Oxidase (GOD) 14.8% 2.Potassium ferricyanide 39.5%

SECTION 10: EXECUTIVE 510(k) SUMMARY

Similarities	
	3.Non-reactive ingredients 45.7%
HCT Range	20-60%
Interferences	Ascorbic acid > 5 mg/dL Cholesterol > 600 mg/dL
Unit of Measurement	mg/dL
Open Vial Shelf Life	3 months
Test Time	5 seconds
Coding	Auto coding
Operating Temperature Range	50 ~104 ℉ (10 ~ 40℃)
Operating Relative Humidity Range	10 ~ 90%
Operating Altitude	Up to 10,000 ft
Test Strip Storage Conditions	39 ~86 ℉ (4 ~ 30℃), 10 ~ 90% relative humidity
Meter Storage Conditions	14 ~140 ℉ (-10 ~ 60℃)
Memory Capacity	500 blood glucose test results with date and time
Control Solution	2 levels (Level 2 and 4, GC550)
Performance	Both devices passed same acceptance criteria for bench performance: precision, linearity and interferences as well as clinical performance: a lay-user trial.

SECTION 10: EXECUTIVE 510(k) SUMMARY

Differences		
	iGlucose Blood Glucose Monitoring System	**GE Blood Glucose Monitoring System 333, k143387**
Indications for Use	The iGlucose 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. The iGlucose Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The iGlucose 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 iGlucose Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. The iGlucose Blood Glucose Test Strips are for use with the iGlucose Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.	The GE Blood Glucose Monitoring System 333 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE Blood Glucose Monitoring System 333 is intended to be used by a single person and should not be shared. The GE Blood Glucose Monitoring System 333 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 GE Blood Glucose Monitoring System 333 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The GE Blood Glucose Test Strips 333 are for use with the GE Blood Glucose Meter 333 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.
Power Supply	Rechargeable battery (3.7V, 1,000mAh Li-Ion)	Two 1.5V (AAA) batteries
Meter Dimensions	104 mm × 49.8 mm × 16.5 mm	85 mm × 57 mm × 22.5 mm
Meter Weight	85.0 ± 5 g with battery	81.0 ± 5 g with batteries

SECTION 10: EXECUTIVE 510(k) SUMMARY

Differences		
	iGlucose Blood Glucose Monitoring System	**GE Blood Glucose Monitoring System 333, k143387**
Battery Life	About 500 tests per battery charge without use of data transmission. Number of uses is reduced and varies when data is transmitted.	About 800 tests per battery life
LCD Display Area	36.6 mm × 49 mm	39 mm × 39.5 mm
Data Transmission	GSM	Bluetooth 4.0 (Low energy)
Power Saving	Automatically turns to standby mode.	Turns to standby by pressing the main button for 3 seconds.
Backlight	Yes	No
Error Messages	Spelled out on meter display	A numerical code is displayed
Interferences	Uric acid > 9 mg/dL	Uric acid > 10 mg/dL

The indications for use statement for the two devices is the same apart from limiting the iGlucose Blood Glucose Monitoring System to testing capillary blood samples from the fingertip only and thus eliminating the risk of lag in blood glucose levels of samples obtained from alternative body sites. Such lag may be present when going through a rapid change in blood glucose concentration. The predicate device lists testing of samples from the fingertips, forearm or palm.

There is also no change to the fundamental scientific technology of the device. The structure, function and performance of the blood glucose monitoring module in the two devices and the structure, function and performance of their accompanying test strips is the same.

10. Standards /Guidance Documents Referenced

- CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- Third Edition(2014)
- CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2010)

- CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2014)
- IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (2001)

11. Performance Characteristics

Bench studies including evaluation of analytical performance as well as clinical performance studies were conducted and passed acceptance criteria. Software verification testing was carried out to ensure all meter functions and displayed error messages perform as intended.

a. Precision Evaluation Study

Following CLSI EP05-A3, repeatability testing was conducted over 10 days using 5 venous blood samples with glucose concentrations spanning the measuring range. Each measured in 10 replicates with 3 test strips lots and 10 meters. Intermediate precision testing was conducted over 10 days using 3 glucose control solutions each measured in 10 replicates with 3 test strips lots and 10 meters. A total of 1500 tests were performed for the repeatability evaluation and 900 for the intermediate precision evaluation. iGlucose meter results of venous blood samples were compared to those obtained by the YSI 2300 analyzer as the reference method.

(i) Repeatability evaluation

Sample	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers (n)	300	300	300	300	300
(2) Mean mg/dL (mmol/L)	44.4 (2.5)	97.6 (5.4)	132.5 (7.4)	213.2 (11.8)	364.0 (20.2)
(3) SD mg/dL (mmol/L)	1.6 (0.09)	2.0 (0.11)	2.3 (0.13)	3.5 (0.19)	5.4 (0.30)
(4) CV (%)	3.6%	2.1%	1.8%	1.6%	1.5%

(ii) Intermediate Precision evaluation

Glucose levels	CS-L	CS-N	CS-H
(1) Total test numbers (n)	300	300	300
(2) Mean mg/dL (mmol/L)	42.7 (2.4)	96.7 (5.4)	274.3 (15.2)
(3) SD mg/dL (mmol/L)	1.2 (0.07)	2.0 (0.11)	4.6 (0.26)
(4) CV (%)	2.8%	2.0%	1.7%

The results of both repeatability and intermediate precision testing demonstrate that the performance of the iGlucose meter falls within acceptance criteria that are equivalent to those produced by the predicate device.

b. Linearity Evaluation Study

Following CLSI EP6-A, linearity testing of the measuring range was conducted using 3 lots of iGlucose blood glucose test strips. Venous blood samples were spiked to 15 levels of glucose concentrations ranging from 0 to 640 mg/dL and the iGlucose meter test results were compared to those obtained from the YSI 2300 analyzer as the reference method.

A linear regression analysis of the glucose measurements resulted in a mean slope ranging from 0.9808 to 0.9952 and an R^2 value of 0.9996 to 0.9997. The results support the claim that the iGlucose Blood Glucose Monitoring System is linear between 20 and 600 mg/dL, a claim equivalent to that made for the predicate device.

c. Interferences - Endogenous/Exogenous Substances

Interference testing followed the CLSI EP7-A2. A total of 19 potential interfering substances were evaluated using 3 lots of test strips at 2 glucose concentrations of venous blood samples, 5 replicates each.

Study results indicate that iGlucose meter measurements of samples containing ascorbic acid (> 5 mg/dL), cholesterol > 600 mg/dL), and uric acid (> 9 mg/dL) resulted in biases greater than ±10% at normal glucose concentrations. These iGlucose meter limitations were equivalent to those found for the cleared predicate device. The results of the 16 remaining potential interfering substances were within acceptance criteria for both normal and high glucose concentrations.

d. Interferences - Hematocrit

Hematocrit levels were evaluated using 3 lots of blood glucose test strips. Samples were prepared ranging in HCT from 20 to 60% at 6 glucose concentration levels of venous blood samples, 5 replicates each. The iGlucose results were compared to the YSI 2300 analyzer as the reference method.

Study results indicate that the measurements of the iGlucose meter were within acceptance criteria for the entire HCT range of 20-60%, a claim equivalent to the one made for the cleared predicate device.

e. Sample Volume

A study was conducted to evaluate sample volumes using 3 lots of blood glucose test strips. Venous blood samples were tested at 3 glucose concentration levels and at 9 sample volumes ranging from 0.60 to 3.0 µL.

Study results demonstrated that when sample volumes were less than 0.70µL, the iGlucose meter displayed an error message. At sample volumes greater than 0.75µL, all iGlucose meter test results were within the acceptance criteria of ±10% compared to reference measurements. The results support a minimum sample volume of 0.75 µL for the iGlucose meter, a claim equivalent to that made for the predicate cleared device.

f. Other Bench Performance studies

Additional bench studies were conducted and all passed acceptance criteria including:

- **Traceability**. The calibration of the iGucose Test Strips was traced to a NIST, SRM 917c glucose standard
- **Accurate meter display of Hi and Lo**. Three meters were tested with check keys of known conductivity to elicit an out of range High and an out of range

Low reading, 10 replicates each. All test results passed and complied with acceptance criteria.

- **Temperature and Humidity Effects**. The operating temperature range and operating relative humidity (RH) were evaluated placing the iGlucose meter and strips in environmental chambers varying in temperature between 10 and 40℃ and between 10 and 95% RH. Testing included 3 test strip lots and two concentrations of blood samples (normal and high), each in 5 replicates. iGlucose measurements were compared to those obtained by the YSI 2300. Results from all testing conditions met acceptance criteria and support a claim of 50 ~104 ℉ (10 ~ 40℃) for the operating temperature and 10 ~ 90% for the RH.

- **Altitude Effects.** The effect of altitudes on the performance of the iGlucose Test strip was evaluated using both control solutions and made up venous blood samples. Testing was conducted at altitudes varying between 0 and 10745 ft. At each altitude, iGlucose blood test results were compared to those of the YSI 2300. The results met acceptance criteria and support the claim that the iGlucose system can be operated at altitudes up to 10,000 ft.

- **Cleaning and Disinfecting.** The effect of the CaviWipes Disinfecting Towelettes was evaluated on five iGlucose meters following cleaning and disinfecting cycles after testing blood samples. Robustness studies were performed demonstrating that there was no change in performance or in external materials of the meter after cycles of cleaning and disinfecting with the CaviWipes Disinfecting Towelettes. The robustness studies were designed to simulate 5 years of multiple use by a single patient.

- **Virucide Efficacy.** The efficacy of the recommended disinfection against Hepatitis B virus (HBV) was evaluated on the materials of the iGlucose meter. Three lots of each material were evaluated and analytical studies included limit of detection (LoD), limit of blank, recovery, interference and, neutralization. A 2 minutes contact time of meter materials with the CaviWipe Disinfecting Towelettes produced results below the LoD and demonstrate effective inactivation of HBV when used to disinfect the iGlucose meter materials.

- **Test Strip stability**. Open vial and shelf life stability of the iGlucose test strip are assessed using real time and accelerated studies. Protocol and acceptance criteria support the claimed stability durations when stored at 4-30^{0}C and at a relative humidity of up to 90%.

- **Readability Assessment of labeling**: A Flesch-Kincaid reading level assessment was conducted demonstrating that the User's Manual, the Getting Started Guide and the Test Strip Insert were written at or below an 8th grade reading level.

g. Method Comparison - Lay-User Trial

A Lay-User trial was performed in a US clinic to ensure the modified device meets user requirements and to demonstrate the ability of subjects to self-train and self-measure their blood glucose levels using the iGlucose Blood Glucose Monitoring System. iGlucose test results were compared to those obtained by the Yellow Springs Instrument YSI 2300 Plus as the reference method, ClinicalTrials.gov Identifier: NCT02709707.

A total of 153 subjects participated; most with a diagnosis of diabetes, either type 1 or type 2 of various duration, 23 were subjects naive to SMBG devices, 6 subjects presented with blood glucose levels <75 mg/dL while 13 were above 250 mg/dL. The HCT levels ranged from 34-64% and the blood glucose concentration spanned the range of 47 to 544.5 mg/dL. Twelve iGlucose Blood Glucose meters participated in the study.

iGlucose vs. YSI for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
33.3% 2/6	83.3% 5/6	100.0% 6/6

iGlucose vs. YSI for glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%
43.5% 64/147	81.6% 120/147	95.2% 140/147

Linear regression results of the iGlucose comparison to the YSI (n=153) were:

Y= 1.000X - 3.21 with a correlation Coefficient of 1.00

12. System descriptions

a. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ___X__ or No_____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes ___X___ or No_____

b. Software Validation

Software testing was conducted based on the level of concern that was identified using FDA's Guidance on Software validation. Analysis of the iGlucose meter test results demonstrate that both meter functionality as well as the display of the appropriate error messages, all perform as intended.

13. Electromagnetic Compatibility and Electrical Safety

Electrical Safety test followed IEC61010-1. Testing results passed acceptance criteria as prescribed by each standard.

14. Expected Values/Reference Range:

The fasting adult blood glucose range for a person without diabetes:

Before meals <100 mg/dL

After meals <140 mg/dL

Reference: American diabetes association. Standards of medical care in diabetes-2016. 2016;39 (supp. 1 diabetes Care):S16

15. Proposed Labeling

A User's Manual, a Getting Started Guide and a Test Strip Insert are provided and as evidence by the Lay User trial, labeling instructions are adequate and satisfy the requirements of 21 CFR Part 809.10.

16. Conclusion

The iGlucose Blood Glucose Monitoring System, is substantially equivalent to the predicate device, the Bionime GE Blood Glucose Monitoring System 333, k143387, based on the substantial equivalence in the Indication for Use Statement, the substantial equivalence in the Fundamental Scientific Technology and based on both bench and clinical performance testing. The differences between the proposed device and the predicate device do not raise new issues of safety and effectiveness.