April 13, 2018

i-SENS, Inc.
Joon Ho Jung
RA Team Manager
43, Banpo-daero 28-gil, Seocho-gu
Seoul, 06646
Korea

Re: K170463
Trade/Device Name: KetoSens Blood β-Ketone Monitoring System
KetoSens Multi Blood β-Ketone Monitoring System
Regulation Number: 21 CFR 862.1435
Regulation Name: Ketones (nonquantitative) test system C
Regulatory Class: Class I, meets limitation of exemptions 21 CFR 862.9(c)(5)
Product Code: JIN
Dated: April 3, 2018
Received: April 10, 2018

Dear Joon Ho Jung:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
k170463

Device Name
KetoSens Blood β-Ketone Monitoring System

Indications for Use *(Describe)*
KetoSens Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood samples drawn from the fingertip. The KetoSens Blood β-Ketone Monitoring Systems are for self-testing outside the body (for in vitro diagnostic use) in the home as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system is intended to be used by a single person and should not be shared.

The KetoSens Blood β-Ketone Test Strips work with the KetoSens Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip.

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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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)*
k170463

Device Name
KetoSens Multi Blood β-Ketone Monitoring System

Indications for Use *(Describe)*
KetoSens Multi Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood from the fingertip and venous EDTA whole blood. KetoSens Multi Blood β-Ketone Monitoring System is intended for in vitro diagnostic use and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system should only be used with single-use, auto-disabling lancing devices.

The KetoSens Multi Blood β-Ketone Test Strips work with the KetoSens Multi Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip and venous whole blood drawn in professional healthcare settings.

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

1. Introduction

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1.1 Type of 510(k):	Traditional 510(k)
1.2 Submitter Information:	i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul, Korea Tel.) +82-2-910-0453 Fax) +82-2-942-2514 e-mail: jhjung@i-sens.com Contact Person: Joon Ho Jung
1.3 Prepared Date:	April 3, 2018

2. Device Name

2.1 Trade Name	KetoSens Blood β-Ketone Monitoring System KetoSens Multi Blood β-Ketone Monitoring System
2.2 Classification Name	JIN - Class I, 21 CFR 862.1435 Ketones (nonquantitative) test system Meets limitations of exemptions 21 CFR 862.9(c)(5)
2.3 510k Number	K170463

KetoSens Blood β-Ketone Monitoring System and KetoSens Multi Blood β-Ketone Monitoring System are essentially the same product in exception to the product name. The two systems include the same meter, test strips, and control solution with the only difference in the names due to the different indications for use (single vs. multiple-patient use). Due to the nature of the similarities, the candidate device's name of KetoSens Blood β-Ketone Monitoring System will be used as a representative of the two devices in this submission.

3. Device Description

The KetoSens Blood β-Ketone Monitoring System/KetoSens Multi Blood β-Ketone Monitoring System consists of a meter, single use test strips, and control solutions with two different β-Ketone concentrations ("Control A" and "Control B" ranges).

The KetoSens Blood β-Ketone Monitoring System/KetoSens Multi Blood β-Ketone Monitoring System is based on an electrochemical biosensor technology (electrochemical). The System measures the Blood β-Ketone level in whole blood samples using a small electrical current generated in the test strips.

The following items are included in the The KetoSens Blood β-Ketone Monitoring System:

- 1 KetoSens Blood β-Ketone Meter
- 1 Lancing device
- 10 Lancets
- Carrying Case
- 1 Owner's Booklet
- 1 Quick Reference Guide
- 2 Batteries (3.0V lithium batteries)

The following items are included in the The KetoSens Multi Blood β-Ketone Monitoring System:

- KetoSens Multi Blood β-Ketone Meter
- 1 Owner's Booklet
- 2 Batteries (3.0V lithium batteries)
- Carrying Case

The following items is compatible with the KetoSens Blood β-Ketone Monitoring System and KetoSens Multi Blood β-Ketone Monitoring System and is available separately.

- KetoSens (Multi) Blood β-Ketone Test Strips
- The KetoSens β-Ketone Control Solution (Level A and B)

4. Intended Use

4.1 KetoSens Blood β-Ketone Monitoring System

KetoSens Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood samples drawn from the fingertip. The KetoSens Blood β-Ketone Monitoring Systems are for self-testing outside the body (for in vitro diagnostic use) in the home as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system is intended to be used by a single person and should not be shared.

The KetoSens Blood β-Ketone Test Strips work with the KetoSens Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip.

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4.2 KetoSens Multi Blood β-Ketone Monitoring System

KetoSens Multi Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood from the fingertip and venous EDTA whole blood. KetoSens Multi Blood β-Ketone Monitoring System is intended for in vitro diagnostic use and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system should only be used with single-use, auto-disabling lancing devices.

The KetoSens Multi Blood β-Ketone Test Strips work with the KetoSens Multi Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip and venous whole blood drawn in professional healthcare settings.

5. Substantial Equivalence Information

The candidate devices are comparable and substantially equivalent to the predicate device.

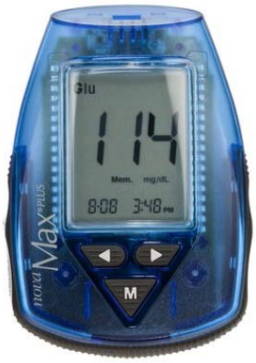
5.1 Predicate Device Name Nova Max Plus Blood Glucose and β-Ketone Monitoring System

- Nova Max Blood Glucose and β-Ketone Monitor
- The Nova Max Plus Ketone Test Strips

3.2 Predicate 510(k) Number k091547

6. Comparison with Predicate Devices

Table 1. The Composition Comparison of the Candidate Devices with the Predicate device

Device Name	Nova Max Plus Blood Glucose and β-Ketone Monitoring System *(Predicate device)*	KetoSens Blood β-Ketone Monitoring System *(Candidate device)*
Meter		

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Device Name	**Nova Max Plus Blood Glucose and β-Ketone Monitoring System** ***(Predicate device)***	**KetoSens Blood β-Ketone Monitoring System** ***(Candidate device)***
Test Strips		

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6.1 Similarities and Differences

The candidate device and the predicate device (Ketone) are classified under 21 CFR 862.1435, which states: "A ketones (nonquantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes." The predicate device has the capacity to measure both glucose as well as β- ketone in blood, whereas the candidate device only measures β- ketone. Substantial equivalence is claimed for the ketone measurement parameter of the predicate device since the intended use of the devices are identical in terms of measuring ketone, and the indications only differ in glucose measuring capabilities between the candidate device and the predicate device.

The intended use for Ketone, operating principle, fundamental scientific technology of the candidate device are same as the predicate device. The list of similarities and differences between the candidate device and the predicate device are shown in Table 2:

Table 2. The Similarities and Differences between the Candidate Devices and the Predicate Device

Item	Nova Max Plus Blood Glucose and β-Ketone Monitoring System *(Predicate device)*	KetoSens Blood β-Ketone Monitoring System *(Candidate device)*
Intended use		
Intended use	The Nova Max Plus Blood Glucose and β-Ketone Monitoring System Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Blood Glucose and β-Ketone Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm and palm and β-hydroxybutyrate (β-ketone) in capillary whole blood from the finger only.	Single-patient use KetoSens Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood samples drawn from the fingertip. The KetoSens Blood β-Ketone Monitoring Systems are for self-testing outside the body (for in vitro diagnostic use) in the home as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system is intended to be used by a single person and should not be shared. The KetoSens Blood β-Ketone Test Strips work with the KetoSens Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip.

	The Nova Max Plus Ketone Test Strips are intended for use only on the Nova Max Plus Blood Glucose and β-Ketone Monitor. Nova Max Plus Ketone Control Solutions are intended for use with Nova Max Plus Blood Glucose and β-Ketone Monitor and Nova Max β-Ketone Test Strips as a quality control check to verify the accuracy of blood ketone test results. There are three levels of controls, (Levels 1,2 and 3).	The KetoSens β-Ketone Control Solutions are intended for use with the KetoSens Blood β-Ketone meter and KetoSens Blood β-Ketone test strip to check that the meter and the test strip are working together properly and that the test is performing correctly. <u>Multiple-patient use</u> KetoSens Multi Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood from the fingertip and venous EDTA whole blood. KetoSens Multi Blood β-Ketone Monitoring System is intended for in vitro diagnostic use and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system should only be used with single-use, auto-disabling lancing devices. The KetoSens Multi Blood β-Ketone Test Strips work with the KetoSens Multi Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip and venous whole blood drawn in professional healthcare settings. The KetoSens β-Ketone Control Solutions are intended for use with the KetoSens Multi Blood β-Ketone meter and KetoSens Multi Blood β-Ketone test strip to check that the meter and the test strip are working together properly and that the test is performing correctly.
Fundamental scientific technology		
Operating principle	β-hydroxybutyrate (β- ketone) is converted by β-hydroxybutyrate dehydrogenase and the magnitude of	Same

	electrical current resulting from this enzymatic reaction is proportional to the amount of β-hydroxybutyrate present in the sample.	
Assay method	Electrochemical	Same
Active reagent	β-hydroxybutyrate dehydrogenase	Same
Test measured	Blood Glucose and β-Ketone	Blood β-Ketone
Technical specifications		
Sample type	Fresh capillary whole blood (fingertip)	Fresh capillary whole blood (fingertip) Venous EDTA whole blood (multi-patient use only)
Hematocrit range	25%-60%	20%-55%
Operating Temperature Range	59°F – 86°F	50 °F ~ 104 °F
Operating Relative Humidity	10%- 90% RH	Same
Test time (sec.)	10	8
Memory capacity	Up to 400	Up to 1,000
Power source	3 volt coin cell battery CL 2450	Two 3.0 V lithium batteries (CR2032)
Weight	2.65 oz	2.53 oz (with batteries)
Test range	0.1 – 8.0 mmol/L	Same
Controls	Nova Max Max Plus Ketone Control Solutions (Levels 1, 2, and 3)	KetoSens β-Ketone Control Solutions (Level A and B)
Coding	No User Input required for Nova Max	No coding required (Automatic code identification)

7. Risk Analysis

We have performed a risk analysis to confirm that risks determined from Preliminary Risk Analysis are reduced or lowered on their probability and severity and to show detailed countermeasures including user manual information, warning, indication and design. Based on risk analysis results, we've conducted the performance evaluations and validation tests to confirm the safety and effectiveness of the candidate device.

8. Validation Activity Summary for the Candidate Device

We have conducted the following validation tests to confirm that the candidate device works properly. Table 4 is the summary of the software validation test results for the candidate device. The tests were conducted for KetoSens Blood β-Ketone Monitoring System software.

Table 3. Software Validation Summary

Test ID and name	Validation activities descriptions	Test results summary
MR16-014_3~ 06 **Performance Test (Drop, Vibration, Temperature and Humidity exposure limits tests)**	Test the performance of meter by dropping, vibrating, and exposing to high or low temperature and high humidity. After the test, check the measurement and operation performance.	Measurement and operation performance of all meters passed the tests.
BKM-031F-R021-3 **Software Function Test**	Test the performance of meter based on set criteria.	100% Compliance
BKM-031F-R022-3 **Memory Test Report**	1st Test is to confirm if the meter operates correctly in full occupied memory condition. 2nd Test is to confirm if the memory records and recalls the measured data and calculates average data correctly. 3rd Test is to confirm if the meter calculates average value on leap year correctly.	Average calculated by meter software exactly matched with average calculated manually.
BKM-031F-R023-3	To check if the clock is running accurately for a period of time	It is confirmed that the time differential between the meter and international

Test ID and name	Validation activities descriptions	Test results summary
Time Test Report **BKM-031F-R024-3** **DAC Function Test Report**	To verify that the reference voltage of the work electrode is 200 mV.	standard time is within ±15 sec. Therefore, Time function of the meter has been verified. Test result shows that DAC function of the meter has been verified through 10 meters. Therefore, DAC function of the meter has been verified.
BKM-031F-R025-3 **Measurement Timing and ADC Test Report**	To verify if the Measurement timing and ADC function works correctly corresponding to the requirement specification.	Test results confirmed that Measurment timing and ADC function of KetoSens has been verified.
BKM-031F-R026-3 **Code Identification Test Report**	To verify the automatic code identification (no coding) function of the meter works properly.	Test result shows that code #1~15 have been correctly identified by all meters.
BKM-031F-R027-3 **Power Consumption Test Report**	To verify the power consumption in various modes of the meter works properly.	Test result confirmed that the meter has been verified through 10 meters.
BKM-031F-R028-3 **Battery Lifetime Test Report**	To verify capable testing times on a continuous measurement condition.	Estimation of the number of times it is capable of testing based on the electrical current consumption and it is possible test about 7320 times. The actual measurement testing was conducted with 2EA the samples. It is assured that the model is capable of testing 3000 times.

9. Performance Evaluation Summary of the Candidate Device

9.1 Repeatability Test (Report No. BKM-031F-R001)

The purpose of repeatability test is to confirm the precision of KetoSens Blood β-Ketone Monitoring System through evaluating test results of blood

samples obtained by the same user using multiple meters and strip lots.

Summary results of repeatability test for the KetoSens Blood β-Ketone Monitoring System

Concentration (mmol/L)	N	Mean (mmol/L)	SD (mmol/L)	%CV
0.4	300	0.39	0.027	6.8
1.1	300	1.08	0.056	5.1
3.4	300	3.38	0.126	3.7
5.2	300	5.16	0.182	3.5
6.9	300	6.91	0.248	3.6

Conclusion:
The pooled SD of concentration intervals 1, 2 were 0.027, 0.056mmol/L respectively that were below 0.075 mmol/L. The pooled CV % of concentration intervals 3, 4 and 5 were 3.7, 3.5 and 3.6%, respectively that were below 5.0 %.

9.2 Intermediate Precision Test (Report No. BKM-031F-R002)

The purpose of this intermediate precision test is to evaluate the degree of precision between other test dates, other users, and results tested with other meters in a similar environment using KetoSens Blood β-Ketone Monitoring System (BKMS) and control solution.

Organized results for each lot and results summed up

Control Level	N	Mean (mmol/L)	SD (mmol/L)	%CV
Level 1	600	0.63	0.049	7.7
Level 2	600	2.23	0.085	3.8
Level 3	600	4.04	0.173	4.3

Conclusion:
The pooled SD for concentration interval 1 was 0.049mmol/L that is less than 0.075mmol/L, and the pooled CV for interval 2, 3 were 3.8, 4.3, respectively that are below 5.0 %.

9.3 Linearity Test (Report No. BKM-031F-R003)

The purpose of conducting linearity test is to demonstrate the measurable concentration range (from 0 mmol/L to 8.0 mmol/L) of KetoSens Blood β-Ketone Monitoring System and confirm linearity through Linearity Study.

Table 3. Summary results of Linearity test

Strip lot. ML07KEA05B : $y = 1.0034x - 0.0145$, $r^2 = 0.9987$
Strip lot. ML07KEA10C : $y = 1.0250x - 0.0466$, $r^2 = 0.9982$
Strip lot. ML08KEA07B : $y = 1.0209x - 0.0323$, $r^2 = 0.9982$
Total 3 strip lots: $y = 1.0159x - 0.0303$, $r^2 = 0.9985$

Conclusion:
Linearity test was conducted by measuring the ketone level in the whole blood samples using 3 lots of test strips. These results were able to obtain the following linear equation and the coefficient of determination (r^2) was able to confirm a high linear correlation above 0.95.

9.4 System Accuracy Test (Report No. BKM-031F-R004)

The purpose of conducting system accuracy test is to confirm the accuracy of KetoSens Blood Ketone Monitoring System (BKMS) through clinical evaluation using capillary and venous blood samples. The accuracy of KetoSens is evaluated with capillary blood and venous whole blood samples collected from a minimum of 200 samples. Each sample is evaluated with each of strip lots on one meters run with the KetoSens BKMS and with the standard measurement.

Summary results of system accuracy test (Capillary blood)

Item	Result		
ketone concentration < 1.5 mmol/L	Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.3 mmol/L

	163/171(95.3%)	169/171(98.8%)	170/171(99.4%)	
ketone concentration ≥ 1.5 mmol/L	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
	11/33 (33.3%)	23/33 (69.7%)	33/33 (100%)	33/33 (100%)

All of 204 capillary blood samples (100 %) fell within either ± 0.3 mmol/L of the average measured values of the reference measurement procedure at ketone concentrations < 1.5 mmol/L or within ± 20 % at ketone concentrations ≥ 1.5 mmol/L.

Summary results of system accuracy test (Venous blood)

Item	Result			
ketone concentration < 1.5 mmol/L	Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.3 mmol/L	
	166/169(98.2%)	168/169(99.4%)	169/169(100%)	
ketone concentration ≥ 1.5 mmol/L	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
	18/35 (51.4%)	28/35 (80.0%)	34/35 (97.1%)	35/35 (100%)

All of 204 venous blood samples (100 %) fell within either ± 0.3 mmol/L of the average measured values of the reference measurement procedure at ketone concentrations < 1.5 mmol/L or within ± 20 % at ketone concentrations ≥ 1.5 mmol/L.

9.5 Hematocrit effect test (Report No. BKM-031F-R005)

The purpose of this hematocrit effect test is to evaluate the effect various hematocrit levels have on blood ketone testing of KetoSens Blood β-Ketone Monitoring System (BKMS). Five different hematocrit levels (20, 30, 42, 50 and 60%) are tested to evaluate the effect of hematocrit level on measurement of ketone concentration. Each of 5 different ketone intervals (in Table 2) is prepared in five different hematocrit levels. The ketone concentration is measured using 30 meters and 3 lots of test strips. 10 meters are assigned to each strip lot.

Summary results of hematocrit effect test

Range (mmol/L)	Average of 3 lots difference (Hct 20 ~ 60%)
0.0 to 0.8	-0.09~0.02
1.0 to 2.0	-7.39~7.83
2.5 to 3.5	-10.33~9.05
4.0 to 5.0	-13.49~10.72
5.5 to 6.5	-15.02~8.73

Conclusion:
The hematocrit biases of KetoSens BKMS evaluated (-0.09 ~ 0.02) mmol/L at interval 1, (-7.39 ~ 7.83%) at interval 2, (-10.33 ~ 9.05%) at interval 3, (-13.49 ~ 10.72%) at interval 4 and (-15.02 ~ 8.73%) at interval 5 of hematocrit levels 20 ~ 60%. Thus, the KetoSens BKMS is safe to use with samples containing various levels of hematocrit.

9.6 Consumer Study (Report No. BKM-031F-R007)

The purpose of conducting Consumer Study is to evaluate the readability of the user's manual, and usability of KetoSens Blood Ketone Monitoring System (BKMS) with accuracy in actual conditions of use. Target users are from various backgrounds in age, gender, educational levels and etc. Study subjects are provided with KetoSens BKMS user manual and are allowed to read through the guidelines before using the meter. Study subjects perform ketone testing on their own and their testing results are to be compared with the Rx Imola reference values, and also BKMS results obtained by trained staff.

General user test results

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.3 mmol/L
183/185(98.9%)	185/185(100%)	185/185(100%)

Trained user test results

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.3 mmol/L

185/185(100%)	185/185(100%)	185/185(100%)

Conclusion:

Total of 185 general users participated in this study. Test subjects were able to perform ketone testing using KetoSens BKMS on their own by referring to the guidelines in the user manual. These results were compared with Rx Imola reference results and KetoSens BKMS satisfied the system accuracy requirements. Test participants were from various backgrounds in terms of age, gender, educational level and etc. Regardlessly, the comprehension level of KetoSens BKMS user manual was high. No one answered the use of KetoSens BKMS was difficult. All of the test participants were able to use KetoSens BKMS correctly and with accurate results. In conclusion, lay users have no problem in using KetoSens BKMS in actual conditions of use, and are able to obtain accurate ketone readings with the help of the guidelines in the user manual. In conclusion, lay users have no problem in using KetoSens BKMS in actual conditions of use, and are able to obtain accurate ketone readings with the help of the guidelines in the user manual.

9.7 Point-of-Care Test Report (BKM-031F-R008)

The purpose of conducting Point-of-care test is to evaluate the usability of KetoSens Multi Blood Ketone Monitoring System by the health care professionals. The accuracy of the BKMS as well as the readability of the user's manual were assessed. This study is conducted at three different sites. The study sites chosen are hospitals for diabetes care. At least two Health Care Professionals perform the blood ketone tests using the KetoSens Multi BKMS at each site. Test participants (sample providers) are diabetic, pre-diabetic and non-diabetic individuals. Health care professionals are provided with the English version of KetoSens Multi BKMS user manual and are allowed to read through the instructions, and after reading through the manual, perform blood ketone testing using KetoSens Multi BKMS from both the capillary and venous blood samples without any help from the trained study staff. The study staff operates the reference equipment and modify the blood sample concentrations. The KetoSens Multi BKMS results are compared against the reference values.

Capillary blood test results

β-Ketone concentration <1.5 mmol/L

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.3 mmol/L
115/124 (92.7%)	121/124 (97.6%)	124/124 (100%)

β-Ketone concentration ≥1.5 mmol/L

Within ±5%	Within ±10%	Within ±15%	Within ±20%
2/12 (16.7%)	8/12 (66.7%)	11/12 (91.7%)	12/12 (100%)

Venous test

β-Ketone concentration <1.5 mmol/L

results Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.3 mmol/L
113/123 (91.9%)	118/123 (95.9%)	121/123 (98.4%)

β-Ketone concentration ≥1.5 mmol/L

Within ±5%	Within ±10%	Within ±15%	Within ±20%
7/13 (53.8%)	12/13 (92.3%)	13/13 (100%)	13/13 (100%)

Conclusion:

POC test is performed by six members of Health Care Professional with KetoSens multi Blood β-Ketone monitoring systems (BKMS) at three sites. They have conducted performance test on KetoSens multi BKMS with a total number of 123 patients, and measured ketone level of patients based only on the manual provided. The KetoSens multi BKMS result is compared against the reference values with Randox Imola, the reference instrument. The comprehension level of KetoSens multi BKMS user manual was high. No one answered the use of KetoSens BKMS was difficult. All of the test HCPs were able to use KetoSens multi BKMS correctly and with accurate results. In conclusion, HCPs have no problems in using the KetoSens multi BKMS in actual conditions of use, and are able to obtain accurate ketone readings with the instructions of the user manual.

7.7 Interference Test (Report No. BKM-031F-R006)

The purpose of this interference test is to evaluate the effect interfering substances have on the blood ketone measurements of KetoSens Blood β-Ketone Monitoring System (BKMS). This interference test is designed to evaluate the effect of various interfering substances in whole blood samples on ketone measurements.

Two ketone concentrations within the intervals (0.0 ~ 0.8, 2.0 ~ 3.5 mmol/L) were prepared in blood samples. 29 types of interferents are tested in this test. Stock solution is prepared for each interferent using PBS (Phosphate Buffered Saline, pH 7.4) as a solvent. In the case of interferents that do not dissolve in PBS, 0.1M NaOH is used. To minimize change in the matrix when stock solution for each interferent is added, it is prepared by concentrating as much as possible. Each sample is divided into two portions (control and test samples) with respect to one interferent.

A concentrated solution of the interferent is added to the test sample and an equal volume of the solvent used for dissolving the interference substance is added to the control sample.

Difference averages interference test

Interferent	Difference (mmol/L or %)					
	Interval 1 (0.0 ~ 0.8 mmol/L)			**Interval 2 (2.0 ~ 3.5 mmol/L)**		
	Strip lot: NF19KEA01 A	Strip lot: NF25KEA01 A	Strip lot: NF26KEA01 A	Strip lot: NF19KEA01 A	Strip lot: NF25KEA01 A	Strip lot: NF26KEA01 A
Acetaminophen	-0.06	-0.03	-0.02	-5.4	-8.3	-7.0
Ascorbic acid	0.06	0.06	0.03	-0.4	-0.4	1.5

Bilirubin	0.03	0.03	0.06	-6.2	-7.4	-7.1
Cholesterol	0.00	0.01	0.01	0.3	1.0	-1.8

Interferent	Difference (mmol/L or %)					
	Interval 1 (0.0 ~ 0.8 mmol/L)			**Interval 2 (2.0 ~ 3.5 mmol/L)**		
	Strip lot: NF19KEA01 A	Strip lot: NF25KEA01 A	Strip lot: NF26KEA01 A	Strip lot: NF19KEA01 A	Strip lot: NF25KEA01 A	Strip lot: NF26KEA01 A
Creatinine	-0.04	-0.03	-0.06	3.0	3.0	4.3
Dopamine	0.02	-0.02	0.01	0.9	-3.6	-0.7
EDTA	-0.02	-0.08	-0.06	-2.4	-5.0	-6.2
Galactose	0.01	-0.03	-0.01	0.1	0.9	2.2
Gentisic acid	-2.04	-2.07	-2.03	4.1	-3.1	-0.9
Hemoglobin	-0.10	-0.10	-0.10	-1.8	-2.2	-3.2
Heparin	0.00	-0.04	-0.07	-2.5	-3.3	-1.8
Ibuprofen	0.04	0.03	-0.01	0.9	0.2	-0.2
L-Dopa	-0.03	-0.05	-0.02	-2.5	-0.7	-2.1
Maltose	0.07	0.04	0.07	3.4	1.0	2.0
Methyldopa	0.03	0.05	0.00	2.0	-0.8	-2.1
Salicylate	0.00	-0.01	-0.07	0.7	-1.2	-0.8
Tolazamide	-0.07	-0.01	0.01	-7.5	-4.6	-2.7
Tolbutamide	-0.03	-0.06	-0.04	4.3	2.2	3.6
Triglycerides	-0.01	-0.04	0.03	0.6	-0.2	3.9
Uric acid	-0.06	0.00	-0.02	-0.4	-2.5	-5.4
Xylose	0.01	0.02	0.00	1.6	0.9	0.2
Glutathione(Red)	-0.02	-0.01	-0.02	-1.4	0.5	-2.0
Catopril	-0.04	-0.02	0.00	-2.3	-3.1	-2.9
Tetracycline	-0.02	-0.05	-0.05	-0.7	-3.2	-3.6
Glucose	-0.03	-0.03	0.01	-1.1	-3.2	0.6
Acetone	-0.01	0.00	0.02	-3.4	1.9	0.7
Acetoacetate	-0.06	0.00	0.00	-0.1	1.0	-1.8

7.8 Altitude test report (Report No. BKM-031F-R009)

The purpose of performing altitude test is to evaluate the capability of KetoSens Blood Ketone Monitoring System (BKMS) to operate normally and to

obtain accurate blood ketone test results at high altitudes (approximately 10,000 feet or 3048m) where the partial pressure of inspired oxygen in the blood decreases.

Conclusion:
KetoSens BKMS did not show significant difference with respect to the Rx Imola equipment, nor with different altitudes at all ketone concentrations. Hence it was confirmed that our BKMS have no systematic response to altitudes and is not significantly affected by lack of atmospheric oxygen up to 10,000 feets (3,048m) above the sea level.

7.9 Operating Condition Test (Temperature and Humidity Exposure) (Report No. BKM-031F-R016)

To evaluate the performance of KetoSens Blood β-Ketone Monitoring System (BKMS) in the specified operating condition (Temperature and humidity range). Operation condition test is evaluating the performance of KetoSens BKMS within the recommended temperature (10 ℃ ~ 40 ℃) and humidity (10 % ~ 90 %) in actual conditions of use.

Conclusion:
Operating condition test was conducted at 9 combined temperature-humidity conditions of 10 ℃, 15 ℃, 23 ℃, 30℃, 40℃ at 10%, 40% and 90% RH. We have confirmed that KetoSens BKMS operates normally at the presented conditions, individual meter measurements giving less than 0.03 mmol/L or 20 % bias from Rx Imola reference results.

7.10 Sample Volume (Report No. BKM-031F-R014)

This is to verify the minimum sample volume used in KetoSens Blood β-Ketone Monitoring System (BKMS) through testing.

Conclusion
Sample volume test was performed using whole blood samples from 3 subjects, each divided three concentration intervals. When 0.4 μL of sample was applied to the strip, Er 4 messages appeared.

7.11 Real lifetime test (Report No. BKM-031F-R018)

The purpose of Real-lifetime shelf-life test is to study the stability of KetoSens test strip through periodical test and to establish expiry date before opening foil (before being put into use). Three lots of test strip foils are stored at three temperatures of recommended strip storage temperatures (4 ℃, 23℃ and 30 ℃) at three humidity levels. The study is conducted using blood samples of three ketone concentrations. At every testing point, strip foil are removed from the designated storage condition. The bias of meter measurement result is compared against the reference values (Rx Imola measurement results) at every time point, and when the bias exceeds 0.225 mmol/L(for ketone concentration under 1.5 mmol/L) or 10% (for ketone concentration above 1.5 mmol/L), the stability of strip is deemed to have diminished, and the study is to be terminated. The study is initially designed to be conducted for more than 18 months.

Conclusion:

Stability of KetoSens strip in foil packaging was studied for 499 days using blood samples of 3 ketone concentrations.

10. Conclusion

Based on the validation study and the performance evaluations, the candidate devices, KetoSens Blood β-Ketone Monitoring System, is as safe and effective as the predicate device. The results of these evaluations demonstrate that the KetoSens Blood β-Ketone Monitoring System is substantially equivalent to the predicate device, Nova Max Plus Blood Glucose and β-Ketone Monitoring System.