510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K242209

B Applicant

Apex Biotechnology Corp

C Proprietary and Established Names

UASure II Blood Uric Acid Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PTC	Class I, reserved	21 CFR 862.1775 - Uric Acid Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Uric acid

C Type of Test:

Quantitative amperometric assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The UASure II Blood Uric Acid Monitoring System is intended for automated and quantitative measurements of blood uric acid level in fresh capillary whole blood drawn from fingertips. It is intended for use outside the body (in vitro diagnostic use) by people with gout as an aid to monitor the effectiveness of uric acid control. The system is intended for singlepatient home use by prescription only and should not be shared.

The UASure II Blood Uric Acid Monitoring System is intended as an aid to monitor blood uric acid level, not to diagnose Hyperuricemia or Gout. The test results obtained from using the UASure II Blood Uric Acid Monitoring System should not be used as a basis to alter medications without first consulting with a physician or a healthcare professional.

The UASure II Blood Uric Acid Monitoring System includes UASure II Meter, UASure II Blood Uric Acid Test Strips, and UASure II Uric Acid Control Solution.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The sponsor describes multiple limitations in their labeling including that the device should not be used if critically ill patients or on neonates. Additionally, the sponsor describes that the device is for single-patient home use by prescription and should not be shared.

D Special Instrument Requirements:

UASure II Meter

IV Device/System Characteristics:

A Device Description:

The UASure II Blood Uric Acid Monitoring System is intended for automated and quantitative measurements of blood uric acid level in fresh capillary whole blood drawn from fingertips. The system is for single-patient home use by prescription and should not be shared. The UASure II Blood Uric Acid Monitoring System consists of the UASure II Meter, UASure II Blood Uric Acid Test Strips, and UASure II Uric Acid Control Solution (Level 1 and Level 2). The UASure II Blood Uric Acid Monitoring System kits include a zippered carry case, a meter, user guide, test strips, lancets (K221570) and lancing device (K221970).

The UASure II Blood Uric Acid Test Strips and UASure II Uric Acid Control Solution can be purchased separately.

B Principle of Operation:

The methodology for the UASure II Blood Uric Acid Monitoring System is amperometry. The uric acid in blood is oxidized and generates a current that can be quantified on the electrode. The current generated at the electrode is proportional to the uric acid concentration of the sample. By measuring the generated current, the concentration of uric acid in the sample is determined.

C Instrument Description Information:

1. Instrument Name:

   UASure II Meter

2. Specimen Identification:

   There is no specimen identification function with this device. Samples are applied directly to the test strip, as they are collected without any identification data.

3. Specimen Sampling and Handling:

   The uric acid test is intended to be used with fresh capillary whole blood from the finger. The whole blood sample is applied directly to the test strip; no handing procedure is required.

4. Calibration:

   The system is calibrated by a code card provided in each box of test strip. The code card is inserted by the user into the meter code card port on the top of the meter. After inserting the code card, the user inserts a test strip to switch on the meter and then waits until the code number appears on the meter display.

5. Quality Control:

   Recommendations relating to Quality Control procedures are described in the labeling. Customer should use UASure II uric acid control solution and the test results should fall within the control range printed on the test strip vial.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Nova Max Uric Acid Monitoring System

B Predicate 510(k) Number(s):

K160990

C Comparison with Predicate(s):

Device & Predicate Device(s):	K242209	K160990
Device Trade Name	UASure II Blood Uric Acid Monitoring System	Nova Max Uric Acid Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the quantitative measurement of uric acid.	Same
Sample Type	Capillary whole blood obtained from the fingertip	Same
Use Environment	Prescription home use	Same
General Device Characteristic Differences		
Methodology	Amperometry using an electrochemical biosensor	Amperometry using a uricase biosensor
Measuring Range	3 - 20 mg/dL	3 -18 mg/dL
Sample Volume	1.5 µL	1.2 µL
Hematocrit Range	20 - 60 %	20 - 65 %

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3 – Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition

CLSI EP17-A2: Evaluation of detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition

Clinical and Laboratory Standards Institute EP07-A3 – Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition

IEC- 61010-1 Edition 3.1 2017-01 Consolidated version- Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements

ISO 14971 Medical devices - Application of risk management to medical devices.

ISO- 15223-1 Fourth edition 2021 -07-Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part1: General requirements.

IEC 62304 Medical device software - Software life cycle processes

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision Study:

The precision study was performed based upon recommendations in the CLSI EP05-A3 Guideline. The total precision was assessed using two levels of control solution. The samples were tested in 2 replicates per run, 2 runs per day for 20 days for a total of 240 measurements (2 replicates x 2 runs x 20 days x 3 lots) per level using three test strip lots and 2 meters. The results are summarized below:

Control Solution	Level 1		Level 2	
Test Strip Lot	Mean (mg/dL)	CV%	Mean (mg/dL)	CV%
Lot 1	4.60	2.9%	8.55	2.5%
Lot 2	4.57	2.8%	8.57	2.5%
Lot 3	4.66	2.8%	8.62	2.5%

Repeatability Study:

Five venous blood samples were tested in one day using ten (10) UASure II meters with 10 replicates for each level on each meter using each strip lot. Three strip lots were used for the study for a total of 300 replicates (10 meters x 10 replicates x 3 strip lots) per concentration level. Results for a representative lot are summarized below:

	Level 1	Level 2	Level 3	Level 4	Level 5
Mean	4.4	6.6	10.5	13.6	18.5
SD	0.2	0.2	0.2	0.4	0.5
CV	4.6%	3.1%	2.3%	3.0%	2.9%

2. Linearity:

Linearity was evaluated using spiked venous whole blood samples with seven different uric acid levels ranging from 2.73-23.73 mg/dL. Three strip lots were used for the study and 20 replicates were run for each concentration level on each strip lot.

The results of the linearity study support the linear range of 2.73-23.73 mg/dL.

3. Analytical Specificity/Interference:

To assess potential interference, venous whole blood samples spiked to two uric acid concentration ranges (4 mg/dL and 9 mg/dL) were used. Each of these samples was divided into two groups: test group (2 level of interferents) and control group (blood without the interferent). The percent difference between the test samples and the control sample was

calculated. The sponsor defined no significant interference as ≤ 10% difference between the test samples and the control samples.

If an interference effect exceeded the acceptance criterion, a dose-response evaluation was performed. A series of test samples (n=5) was prepared by mixing the sample containing the highest concentration of potentially interfering substance and control sample in different proportions.

No interference was observed with the following compounds at the concentrations listed:

#	Interfering substances	Concentration (mg/dL)	#	Interfering substances	Concentration (mg/dL)
1	Ketoprofen	10	7	Triglycerides	1500
2	Diclofenac	5	8	Creatinine	30
3	Indomethacin	10	9	Warfarin	20
4	Allopurinol	10	10	Glucose	1020
5	Hemoglobin	7500	11	Cholesterol	500
6	Bilirubin, conjugated	25	13	Acetylsalicylic acid (Salicylate)	60

The interferents that may affect test results are described below:

#	Interfering substances	Interference concentration
4	Acetaminophen	> 1.0 mg/dL
6	Methyldopa	> 0.1 mg/dL
7	L-Ascorbic acid	> 10 mg/dL
8	Pyruvate	> 1.5 mg/dL
11	Dopamine	> 0.375 mg/dL
12	L-dopa	> 0.35 mg/dL
20	Tolazamide	> 9 mg/dL
21	Ibuprofen	> 15 mg/dL

The limitations section of the device's package insert and user manual explain that if users are taking Acetaminophen or Acetaminophen containing drugs (for example Tylenol, Panadol or certain prescription), and/or if users are taking Methyldopa for treatment of high blood pressure (hypertension), and/or if users are taking drugs contain L-Ascorbic acid, Dopamine, Pyruvate, L-dopa, Tolazamide or Ibuprofen, then they must not use the UASure II System to test their uric acid levels, because they may get inaccurate results with this system.

4. Assay Reportable Range:

The assay's reportable range is 3 to 20 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The system is traceable to commercially available method.

6. Detection Limit:

The sponsor conducted limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) studies which support the claimed lower limit of 3 mg/dL.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

Refer to method comparison study section under B.1.

9. Carry-Over:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A comparison study between the UASure II Blood Uric Acid Monitoring System and the comparator method was conducted using three different strip lots. A total 150 fresh fingertip capillary samples were tested by individuals ranging in age from 19-70 years. All testing was conducted per the instructions for use. The samples tested had uric acid values ranging from 3.03 to 19.84 mg/dL.

Heparinized plasma samples were collected from the individuals and were tested on the comparison method. The data were analyzed using Passing-Bablok regression, and the comparison of the candidate device (Y-axis) with the comparator device (X-axis) are summarized below:

Passing-Bablok: $y = 0.987x + 0.186$, $R = 0.990$

2. Usability Survey:

The lay users were surveyed after the study by means of a questionnaire on the usability of the UASure II Blood Uric Acid Monitoring System and the instructions for use. The questionnaire included user responses regarding ease of use of the system and clarity of the user instructions. The survey results demonstrated that lay users found the system and instructions to be adequate.

3. Readability Assessment:

A Flesch-Kinkaid reading level assessment was conducted by the sponsor which demonstrated that the meter user manual and test strip product inserts were written at or below an 8th grade reading level.

4. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor provided the following information in their labeling.
Normal Blood Uric Acid Readings
Male: 4.0~8.5 mg/dL (238~506 μmol/L)
Female: 2.7~7.3 mg/dL (161~434 μmol/L)

The healthcare professionals will assist users in establishing target ranges for the user and deciding when and how often to test.

F Other Supportive Instrument Performance Characteristics Data:

1. Sample Volume Study:

The nominal fill volume indicated by the labeling of the device is 1.5 μL of capillary whole blood. A study was performed to determine the minimum fill volume of the test strip. Three whole blood samples spiked to different uric acid concentrations (4.26, 9.55, and 18.98 mg/dL) were tested on three strip lots using one uric acid meter. Different volumes of whole blood were added to the test strips to determine the minimum volume to trigger the device to take a reading. 0.8, 1.0, 1.5, 2.0, 2.5, 3.0 μL were tested with three different lots of test strips. The sponsor provided validation studies demonstrating that with blood volumes below 1.5 μL, the

instrument either does not give a result or generates the insufficient sample volume error message.

2. Hematocrit Study:

Three different test strip lots were analyzed at eight different hematocrit levels (20, 25, 30, 35, 43, 50, 55, and 60%) using five venous whole blood samples spiked with uric acid (4.0, 7.6, 10.7, 13.7, and 18.6 mg/dL) on ten different meters. The results were compared to results obtained using the comparator device. The performance of the three lots of test strips demonstrates that the hematocrit levels tested did not affect the performance of the uric acid system. These data support the UASure II Blood Uric Acid Monitoring System's claimed hematocrit range of 20%-60%.

3. Altitude Study:

Ten different meters with venous whole blood samples spiked with uric acid (4.37, 8.12, 10.92, 15.8, and 19.23 mg/dL) were tested at sea level and 3,150 meters (10,335 feet). The results obtained were compared to the comparator device. The provided data support their claims that the system can be used up to altitudes of 10,335 feet (3,150 meters).

4. Test System Operating Conditions – humidity and temperature:

Three different test strip lots were analyzed at combinations of five temperatures (10, 20, 25, 30, 38, ± 2℃) and three humidity (20, 50, and 85%) conditions on ten different meters using four whole blood samples spiked with uric acid (4.7, 9.1, 14.22, and 18.2 mg/dL). The results were compared to results obtained using the comparator device. The uric acid control solutions were also evaluated at the same conditions as the test samples. The provided data support their claims that the meter and the test strips can be used within 50°F~100°F (10°C~38°C) and 20%~85% relative humidity.

5. Pre and Post Cleaning and Disinfection Precision and Accuracy Study:

The UASure II Blood Uric Acid Monitoring System is intended for single-patient use only. Robustness studies were performed by the sponsor demonstrating that there was no change in performance or in external materials of the meters after 1825 cleaning and disinfection cycles with Clorox Healthcare Bleach Germicidal wipes. The robustness studies were designed to simulate 5 years of single patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Disinfection Efficacy/Infection Control Study:

The materials used for manufacturing the UASure II Meters are the same as those used in the AutoSure HT meter (K131750) except for color. The sponsor is leveraging the viral inactivation testing data generated for the AutoSure HT meter (K131750) using Clorox Healthcare Bleach Germicidal wipes (EPA Reg# 67619-12).

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.