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

A. 510(k) Number:

k181675

B. Purpose for Submission:

New device

C. Measurand:

Uric acid

D. Type of Test:

Quantitative amperometric assay

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

FORA MD6 Uric Acid Monitoring System
FORA MD6 Pro Uric Acid Monitoring System

G. Regulatory Information:

Regulation	Classification	Product Code	Panel
21 CFR §862.1775, Uric acid test system	Class I, reserved	PTC uric acid test system for at home prescription use	Clinical Chemistry (75)
21 CFR §862.1775, Uric acid test system	Class I, meets limitations of exemptions 21 CFR §862.9(c)(9)	LFQ uric acid reduction of ferric ion	Clinical Chemistry (75)

H. Intended Use:

1. Intended use:
   See indications for use below.

2. Indications for use:

Prescription home use:

The FORA MD6 Uric Acid Monitoring System is intended for the quantitative measurement of uric acid in capillary whole blood from the fingertip. It is intended for use outside the body (in vitro diagnostic use) by people with hyperuricemia or gout as an aid to monitor the effectiveness of uric acid control. The system is intended for single-patient home use by prescription only and should not be shared. The system should only be used with FORA MD6 Uric Acid Test Strips, and FORA Uric Acid Control Solutions.

The system should not be used to alter hyperuricemia or gout treatment by changing any medication schedule or dosage unless specifically instructed by a healthcare professional.

Prescription use:

The FORA MD6 Pro Uric Acid Monitoring System is intended for the quantitative measurement of uric acid in capillary whole blood from the fingertip. This system should only be used with single-use, auto-disabling lancing devices. It is for in vitro diagnostic use only.

This system is intended for multiple patient use by health care professionals at point of care sites as an aid to monitor the effectiveness of uric acid control in people with hyperuricemia or gout.

3. Special conditions for use statements:

Limitations - FORA MD6 Uric Acid Monitoring System:

For in vitro diagnostic use (for use outside of the body only).

The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!

This system is not for use in patients with abnormally low blood pressure or those who are in shock.

This system should not be used on critically ill patients.

Neonatal Use: This test system must not be used for the testing of neonate.

Limitations - FORA MD6 Pro Uric Acid Monitoring System:

For in vitro diagnostic use (for use outside of the body only).

Healthcare professionals and other users testing multiple patients with this system should handle everything that has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

This system is not for use in patients with abnormally low blood pressure or those who are in shock.

This system should not be used on critically ill patients.

Neonatal Use: This test system must not be used for the testing of neonate.

4. Special instrument requirements:
   FORA MD6 Uric Acid meter
   FORA MD6 Pro Uric Acid meter

I. Device Description:

FORA MD6 Uric Acid Monitoring System:

The FORA MD6 Uric Acid Monitoring System is a portable system consisting of the FORA MD6 Uric Acid meter and FORA MD6 Uric Acid test strips. The system also includes control solutions, lancing device, owner's manual, protective wallet, quick start user guide, daily log book, and warranty card.

FORA MD6 Pro Uric Acid Monitoring System:

The FORA MD6 Pro Uric Acid Monitoring System is a portable system consisting of the FORA MD6 Pro Uric Acid meter and FORA MD6 Pro Uric Acid test strips. The system also includes control solutions, lancing device, owner's manual, protective wallet, quick start user guide, daily log book, and warranty card.

J. Substantial Equivalence Information:

1. Predicate device name:
   Compur Easy Touch Uric Acid Reagent; k832785

2. Predicate 510(k) number:
   See predicate device name.

3. Comparison with predicate:

Similarities and Differences		
Item	Subject Device, FORA MD6 Uric Acid Monitoring System k181675	Predicate Device, Compur Easy Touch Uric Acid Reagent k832785
Intended use	Intended for the quantitative measurement of uric acid.	Same
Measuring range	3.0 to 13.0 mg/dL	0.3 to 20 mg/dL
Specimen type	Capillary whole blood from fingertip	Serum and plasma
Methodology	Amperometry	Enzymatic colorimetric assay
Sample volume	2 µL	25 µL

Similarities and Differences		
Item	Subject Device FORA MD6 Pro Uric Acid Monitoring System k181675	Predicate Device, Compur Easy Touch Uric Acid Reagent k832785
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K. Standard/Guidance Document Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Third Edition.

CLSI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline —Second Edition.

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

IEC 62304 Medical device software - Software life cycle processes.

IEC 62366 Application of usability engineering to medical devices.

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

L. Test Principle:

The uric acid measurement is based on electrochemical biosensor technology and utilizes a nonenzymatic detection through the one electron reduction of ferric ion to produce a current directly proportional to the uric acid concentration.

M. Performance Characteristics:

1. Analytical performance:

Analytical performance studies were conducted using the FORA MD6 Uric Acid Monitoring System. The only differences between the FORA MD6 Uric Acid Monitoring System and FORA MD6 Pro Uric Acid Monitoring System are the intended use and labeling.

a. Precision/Reproducibility:

The precision performance of the FORA MD6 Uric Acid Monitoring System was established following the recommendations in CLSI EP05-A3.

Internal repeatability study
The repeatability of the system was assessed using heparin venous whole blood prepared with two uric acid concentrations and tested on 10 meters and 3 test strip lots. At each concentration, 10 replicates were tested per meter on each of three lots for a total of 300 measurements. The results are summarized below:

		Lot 1	Lot 2	Lot 3	Combined
5 mg/dL	Mean	5.0	4.9	5.0	5.0
	% CV	4.1%	4.2%	4.0%	4.2%
10 mg/dL	Mean	10.2	10.0	9.9	10.0
	% CV	3.0%	3.2%	3.2%	3.3%

Within-laboratory
Within-laboratory precision was assessed using one level of a control solution and two levels of heparin venous whole blood. The samples were tested in 2 replicates per run, 2 runs per day for 20 days for a total of 80 measurements per level using one test strip lot and 4 meters. After each two day period, the whole blood samples were prepared fresh. The results demonstrated %CV levels of less than 4%.

Multi- site precision study

A precision study was conducted at three sites. At each site, 3 operators and 3 meters assayed samples in five replicates per run with one run per day over 5 days for each of 3 test strip lots for a total of 225 measurements per sample. The samples were venous whole blood with two levels of uric acid. After each two day period, the whole blood samples were prepared fresh. All sites used the same samples and test strip lots. The results demonstrated %CV levels of less than 4%.

b. Linearity/assay reportable range:

The linearity of the uric acid test system was assessed following the recommendations in CLSI EP06-A. Linearity of the test system was established using six venous whole blood samples spanning the claimed analytical measurement range of 3.0 to 13.0 mg/dL. Samples with concentrations known relative to each were prepared from a dilution series by combining volumes from a high pool and low pool for uric acid. Each of the samples was measured in replicates of 5 across one run. The measured uric acid concentrations were assessed for a linear response by the polynomial method of CLSI EP06-A. Regression analysis identified that the coefficients for a second or third order polynomial fit were not statistically significant, and therefore the uric acid test system response is not fitted better by a polynomial function, and a linear response was implied. Based on these results, the sponsor concluded that the uric acid test system demonstrate a satisfactory linear response over the claimed range of 3.0 to 13.0 mg/dL. The linear regression summary is given below.

Slope	Intercept	R^2	Range tested
0.996	-0.014	0.995	2.5 – 14.8 mg/dL

Readings outside of measurement range:

Software verification studies were provided to demonstrate that if a uric acid measurement was less than the lower end of the analytical measurement range, a 'Lo' message is displayed. If a measurement exceeded the upper end of the analytical measurement range a 'Hi' message is displayed.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

The FORA MD6 Uric Acid Monitoring System and FORA MD6 Pro Uric Acid Monitoring System are standardized using calibrators with values assigned by an isotope dilution-mass spectrometry method for uric acid.

d. Detection limit:

The detection limit of the FORA MD6 Uric Acid Monitoring System was established by evaluation of the Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ).

LoB: The LoB was analyzed non-parametrically as the 95th percentile of the measurements following the recommendations in CLSI EP17-A2.

LoD: The LoD was analyzed by parametric analysis following the recommendations in CLSI EP17-A2.

LoQ: For the LoQ study, 9 venous whole blood samples with varying low levels of uric acid were prepared and tested using two test strip lots in replicates of two per run with 2 runs per day for 20 days. The LoQ estimate for each reagent lot was determined directly from the concentration versus precision plot with LoQ at the intersection with the %CV goal of 7.5%. The highest LoQ from the two test strip lots was taken as the overall LoQ. The results of the detection limit studies are summarized as follows:

LoB	LoD	LoQ	Analytical Measurement Range
1.3 mg/dL	1.7 mg/dL	2.8 mg/dL	3.0 to 13.0 mg/dL

e. *Analytical specificity:*

Interference testing on the FORA MD6 Uric Acid Monitoring System was evaluated following the recommendations in CLSI EP07-A2.

Interference testing was performed to evaluate exogenous and endogenous substances using venous whole blood spiked to two uric acid levels of 5 and 10 mg/dL. The samples were divided into 2 aliquots: control (with no added interferent) and test (with added interferent at a toxic level or 10 times the known therapeutic level). Each sample was measured in replicates of four using four meters and one test strip lot.

The sponsor defined no significant interference as bias < ± 10% for the test compared to control samples. The following table lists the concentrations of each substance at which no significant interference was detected.

Substance	Highest concentration tested with no significant interference
Acetylsalicylic Acid	50 mg/dL
Acyclovir	3.1 mg/dL
Allopurinol	5 mg/dL
Amitriptylline	0.27 mg/dL
Amoxicillin	12.5 mg/dL
Ampicillin	5 mg/dL
Ascorbic acid	10 mg/dL
Atenolol	10 mg/dL
Bicarbonate	336 mg/dL
Bilirubin, conjugated	25 mg/dL
Bilirubin, unconjugated	40 mg/dL
Cholic Acid	6 mg/dL

Substance	Highest concentration tested with no significant interference
Caffeine	10 mg/dL
Calcium	5 mM
Chloride	140 mM
Clonidine	2 mg/dL
Creatinine	30 mg/dL
Digoxin	0.16 mg/dL
Diphenhydramine	1 mg/dL
Dopamine	5 mg/dL
Enalapril	0.15 mg/dL
Erythromycin	20 mg/dL
Ephedrine HCl	60 mg/dL
Erythromycin	20 mg/dL
Estrone	0.1 mg/dL
Famotidine	0.13 mg/dL
Fluoxetine	0.8 mg/dL
Fructose	1000 mg/dL
Furosemide	2 mg/dL
Gamma-globulin	12000 mg/dL
Glyburide	1.07 mg/dL
Hemoglobin	20 g/dL
Ibuprofen	55 mg/dL
Isomalt	1000 mg/dL
Lactose	1000 mg/dL
Lactitol	1000 mg/dL
Levo – Dopa	20 mg/dL
Lidocaine	6 mg/dL
Magnesium	5 mM
Maltitol	1000 mg/dL
Maltose	1000 mg/dL
Mannitol	1000 mg/dL
Metaproterenol	1.81 mg/dL
Metformin HCl	50 mg/dL
Metoprolol	0.3 mg/dL
Naproxen	100 mg/dL
Nifedipine	0.17 mg/dL
Nortriptyline	0.15 mg/dL
Penicillin	12 mg/dL
pH value 6.7 – 9.8	pH value 6.7 – 9.8
Phenytoin	10 mg/dL
Piroxicam	5 mg/dL
Potassium	10 mM
Salicylic Acid	60 mg/dL
Sodium	200 mM

Substance	Highest concentration tested with no significant interference
Sorbitol	1000 mg/dL
Sulfamethoxazole	120 mg/dL
Sulfate	5 mM
Terfenadine	0.45 mg/dL
Tetracycline	4 mg/dL
Theophylline	25 mg/dL
Triglycerides	1500 mg/dL
Tolbutamide	64 mg/dL
Urea	600 mg/dL
Vancomycin	25 mg/dL
Verapamil	0.45 mg/dL
Vitamin E	20 mg/dL
Warfarin	2 mg/dL
Xylitol	1000 mg/dL
Xylose	1000 mg/dL

The product labeling has the following limitation statements:

FORA MD6 Uric Acid Monitoring System:

► If you take ACETAMINOPHEN or medications containing acetaminophen (Tylenol®, Panadol, certain cold and flu remedies, or certain prescription drugs) then you should know that this medication affects the reliability of your uric acid results. If you are taking acetaminophen then you must NOT use the FORA MD6 Test Strips with the FORA MD6 Uric Acid Monitoring System to test your uric acid levels. If you are unsure, then ask your doctor.

► Your doctor may have prescribed METHYLDOPA for treatment of high blood pressure (hypertension). If you are taking METHYLDOPA, then you must NOT use the FORA MD6 Test Strips with the FORA MD6 Uric Acid Monitoring System to test your uric acid levels, as this medication adversely affects the reliability of your uric acid results. If you are unsure, then ask your doctor.

FORA MD6 Pro Uric Acid Monitoring System:

► Do not use the FORA MD6 Pro Test Strips with the FORA MD6 Pro Uric Acid Monitoring System to test patients who are taking acetaminophen or acetaminophen containing medications (Tylenol®, Panadol, certain cold and flu remedies, or certain prescription drugs). Acetaminophen plasma levels at 3 mg/dL and above cause falsely elevated (positive) uric acid results. A blood plasma concentration of 3 mg/dL is within the normal therapeutic range for acetaminophen.

► Do not use the FORA MD6 Pro Test Strips with the FORA MD6 Pro Uric Acid Monitoring System to test patients who are taking METHYLDOPA (treatment of high blood pressure). Methyldopa blood plasma levels at 0.3 mg/dL and above cause falsely elevated (positive) uric acid results. A blood plasma concentration of 0.3 mg/dL is within the normal therapeutic range for Methyldopa.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The accuracy performance of the FORA MD6 Pro Uric Acid Monitoring System was evaluated in a method comparison study by comparing uric acid measurements for agreement to a comparator method. The prospective study was conducted at three point of care sites. The study recruited 350 adult patients. For each patient, a health care professional collected capillary whole blood by fingerstick and sodium heparin venous whole blood for plasma. Uric acid concentrations were measured in singlicate by the healthcare professional using three meters and three lots of test strips. Comparison uric acid measurements were generated in a clinical laboratory using a comparator method. The sponsor reported that there were no contrived samples. The results of the method comparison study are summarized as follows.

Linear regression analysis

Site	Slope	Intercept	R^2	Range, mg/dL	Number
1	1.0194	-0.0566	0.9771	3.5 to 12.5	114
2	1.0626	-0.3304	0.9748	3.5 to 10.1	119
3	1.0203	-0.1127	0.965	3.1 to 11.1	117
All sites combined	1.0329	-0.1599	0.9727	3.1 to 12.5	350

Individual bias (all sites combined)

Within ±5%	Within ±10%	Within ±15%
74.9% (262/350)	94.6% (331/350)	100% (350/350)

b. Matrix comparison:

Not applicable.

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable.

   b. Clinical specificity:

   Not applicable.

   c. Other clinical supportive data:

   Lay user study for prescription home use:
   A method comparison study was conducted to establish that lay users are able to accurately use the FORA MD6 Uric Acid Monitoring System. The study recruited 399 adult lay users who self tested according to the instruction for use and without assistance. Following completion of the lay user self-test, sodium heparin whole blood for plasma was collected and tested by a laboratory comparator method. The results of the testing by the lay users are given below:

   Linear regression analysis

Slope	Intercept	R^2	Range	Number
0.955	0.25	0.950	3.0 to 12.0 mg/dL	399

   Individual bias

Within ±5%	Within ±10%	Within ±15%
56.4% (225/399)	90.7% (362/399)	100% (399/399)

   Usability survey
   The lay users were surveyed after the study by means of a questionnaire on the usability of the FORA MD6 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.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   The product labeling states to consult your doctor to determine a target range and identifies the following reference values for uric acid:

Female: 2.3 - 6.6 mg/dL
Male: 4.4 - 7.6 mg/dL

Source: Tietz, N.W.(ed), Clinical Guide to Laboratory Tests, 4th Edition, W.B. Saunders, 2006.

N. Instrument Name:

FORA MD6 Uric Acid meter
FORA MD6 Pro Uric Acid meter

O. System Descriptions:

1. Modes of Operation:

   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 _____ or No ___X___

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device.

4. Specimen Sampling and Handling:

   Whole blood is directly applied to the test strip by capillary action, and there is otherwise no special handling.

5. Calibration:

   The product labeling instructs the user to calibrate the meter every time a new vial of uric acid test strips is used. The system is calibrated by coding. The code is entered by the user inserting a code strip into the meter while off and then waiting until the code number appears on the meter display.

The product labeling states that the quantitation whole blood uric acid yields plasma equivalent results.

6. Quality Control:

The sponsor supplies 2 levels of FORA Uric Acid Control Solution. The controls are sold separately.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The Performance Characteristics Section above:

Hematocrit study:
A study was conducted to verify that the uric acid measurements on the FORA MD6 Uric Acid Monitoring System are not affected by hematocrit levels over the range of 20% to 60%. In the study, samples at four uric acid concentrations and 6 hematocrit levels from 20% to 60% were prepared from sodium heparin whole blood. Each samples was measured in 6 replicates using 6 meters and one test strip lot. The effect of hematocrit on the uric acid measurements was evaluated for bias versus a comparator method. The hematocrit level for each sample was measured by a microhematocrit method. The results demonstrated that hematocrit levels from 20% and 60% have no significant impact on the blood uric acid measurements.

Altitude study:
A study was conducted to demonstrate that uric acid measurements on the FORA Advanced GD40 Uric Acid Monitoring System were not affected by altitudes from sea level to 15,000 feet. Venous whole blood samples were spiked to 4 concentrations of uric acid and each tested at 4 atmospheric pressures using a glove box to simulate changes in altitude (0, 500, 11500, and 15000 feet). Each sample was tested with 4 meters and one lot of test strips. The bias at each condition was calculated relative to a comparator method. The results support the claim that altitudes changes from sea level to 11,500 feet have no significant effect on the blood uric acid measurements.

Temperature and Humidity Study:
A study was conducted to validate the operating temperature and humidity claims of the system. In this study, sodium heparin venous whole blood samples at two uric acid levels (5 and 10 mg/dL) were tested in 4 replicates using 4 meters and one test strip lot. Operating conditions were evaluated at following four combinations temperature and humidity extreme conditions in an environmental chamber:

50°F (10°C) and 10% RH
50°F (10°C) and 85% RH
104°F (40°C) and 10% RH
104°F (40°C) and 85% RH
77°F (25°C) and 60% RH

The bias at each condition was calculated relative to a comparator method. The results support the claimed operating temperature range of 50°F (10°C) to 104°F (40°C) at 10% to 85% RH.

Electromagnetic Compatibility:
The information to support electromagnetic compatibility (EMC) performance for the FORA MD6 Multi-Functional meter was reviewed and found acceptable.

Sample Volume Study:
The volume of capillary whole blood required by the test strip is 2.0 µL. A study was performed to verify the sample volume and to verify proper reporting of an error message when the volume is below 2.0. For testing, samples were prepared by spiking sodium heparin venous whole blood at two levels of uric acid (5 mg/dL and 10 mg/dL). Each uric acid sample was tested in replicates of 5 using five meters and one test strip lot across 6 different volumes (1.8, 1.9, 2.0, 2.1, 2.2, 2.3 µL). Results from this study supported the claimed minimum sample volume of 2.0 µL. The study found that for volumes less than 2.0 µL, the meter displayed an error message "E-F", and for volumes of 2.0 µL and greater the system returned correct results.

Infection Control Studies:
The FORA MD6 Uric Acid meter is intended for single-patient use, and the FORA MD6 Pro Uric Acid meter is intended for multiple-patient use.

The information in support of disinfection efficacy was reviewed and found acceptable.

Robustness studies were performed by the sponsor demonstrating that there was no change in performance or in external materials of the meters after 10,950 cleaning and disinfection cycles with Micro-Kill Wipes. The robustness studies were designed to simulate 3 years of multiple-patient use and 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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