510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: k181675

1. Submitter Information

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2. Regulatory information:

Proprietary Name:	FORA MD6 Uric Acid Monitoring System FORA MD6 Pro Uric Acid Monitoring System
Product Code:	PTC - Uric Acid Test System, For At Home Prescription Use LFQ - Acid, Uric Reduction of Ferric Ion
Classification Panel:	Clinical chemistry
Classification:	Class I, reserved (for PTC) Class I, meets limitations of exemptions 21 CFR §862.9(c)(9) (for LFQ)
Regulation Citation:	21 CFR 862.1775 Uric acid test system

3. Primary Predicate Device

Compur Easy Touch Uric Acid Reagent (K832785)

4. Intended 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.

Point-of-care 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

5. Device Description:

FORA MD6/ FORA MD6 Pro Uric Acid Monitoring System includes the FORA MD6/ FORA MD6 Pro Meter, the FORA MD6/ FORA MD6 Pro Uric Acid Test Strips and the Uric Acid Control Solutions.

6. Comparison to the 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 to 13 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 µ L	25 µ L

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7. Test Principle:

FORA MD6/ FORA MD6 Pro Uric Acid Monitoring System utilizes a non-enzymatic uric acid detection approach. Through the reduction of ferric ion, Uric acid produces one electron. An electrical current resulting from this reaction is measured and correlated to uric acid concentration by the meter.

8. Performance Studies:

The performance of the FORA MD6 Uric Acid Monitoring System/FORA MD6 Pro Uric Acid Monitoring System. was studied in the laboratory and in clinical settings by healthcare professional and lay users. The studies demonstrated that the intended users can obtain uric acid results that are substantially equivalent to the current methods for uric acid measurements.

9. Conclusion:

Based on the results of laboratory and clinical studies provided in this submission, FORA MD6 Uric Acid Monitoring System/FORA MD6 Pro Uric Acid Monitoring System. is substantially equivalent to the predicate devices in uric acid testing.